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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA–2017–N–6381]

RIN 0910–AH51

Postmarketing Safety Reports for Approved New Animal Drugs; Electronic Submission Requirements

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

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a final rule to require electronic submission of certain postmarketing safety reports for approved new animal drugs. The final rule also provides a procedure for requesting a temporary waiver of the electronic submission requirement.

DATES: This rule is effective August 28, 2020. For the applicable compliance date, please see section V, ''Effective and Compliance Dates'' in **SUPPLEMENTARY INFORMATION**.

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

FOR FURTHER INFORMATION CONTACT: *With regard to the final rule:* Linda Walter-Grimm, Center for Veterinary Medicine (HFV–240), Food and Drug Administration, 7519 Standish Pl., MPN4, Rm. 2666, Rockville, MD 20855, 240–402–5762, *Linda.Walter-Grimm@fda.hhs.gov.*

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

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I. Executive Summary

A. Purpose of the Final Rule

The purpose of this rulemaking is to require electronic submission of certain postmarketing safety reports for approved new animal drugs and to provide a procedure for requesting a temporary waiver of the requirement.

We require applicants to submit to us postmarketing safety reports of adverse drug experiences and product/manufacturing defects for approved new animal drugs (see § 514.80 (21 CFR 514.80)). An applicant is defined as a person or entity who owns or holds on behalf of the owner the approval for a new animal drug application (NADA) or an abbreviated new animal drug application (ANADA) and is responsible for compliance with applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and regulations (see § 514.3 (21 CFR 514.3)). In addition, a nonapplicant, defined in § 514.3 as any person other than the applicant whose name appears on the label and who is engaged in manufacturing, packing, distribution, or labeling of the product, may elect to submit adverse drug experience reports directly to us (§ 514.80(b)(3)).

The continuous monitoring of new animal drugs affords the primary means by which we obtain information regarding problems with the safety and efficacy of marketed approved new animal drugs, as well as product/manufacturing problems. Postapproval marketing surveillance is important to ensure the continued safety and effectiveness of new animal drugs. Drug effects can change over time and other effects may not manifest until years after the approval.

Finalizing this rule will improve our systems for collecting and analyzing postmarketing safety reports. The change will help us to more rapidly review postmarketing safety reports, identify emerging safety problems, and disseminate safety information in support of our public health mission. In addition, the amendments will facilitate international harmonization and exchange of safety information. This rule also provides a procedure for requesting a temporary waiver of the electronic submission requirement.

B. Summary of the Major Provisions of the Final Rule

The rule amends the records and reports regulation in part 514 (21 CFR part 514) to include the following:

- Procedures relating to the electronic submission of certain postmarketing safety reports for approved new animal drugs; and
- Procedures for requesting a temporary waiver of the electronic submission requirement.

The final rule requires electronic submission for the following reports for approved new animal drugs: (1) 3-day alert reports that applicants elect to submit as a courtesy copy directly to FDA's Center for Veterinary Medicine (CVM) in addition to the requirement they have to submit these reports on paper Form FDA 1932 to the appropriate FDA District Office or local FDA resident post; (2) 15-day alert reports and followup reports; product/manufacturing defect and adverse drug experience reports submitted by nonapplicants who elect to report adverse drug experiences directly to CVM in addition to providing these reports to the applicant; and (3) product/manufacturing defect and adverse drug experience reports (including reports of previously not reported adverse drug experiences that occur in postapproval studies) required

to be submitted as part of the periodic drug experience report. We are replacing the current paper submission process with the electronic submission requirement and a procedure for requesting a temporary waiver of the electronic submission requirement. Finally, the final rule clarifies where to submit reports not required to be submitted electronically. Under the final rule, we continue to require 3-day alert reports to be submitted to the appropriate FDA District Office or local FDA resident post on paper. However, as noted, if in addition to the report an applicant submits on paper Form FDA 1932 to the appropriate FDA District Office or local FDA resident post, an applicant elects to submit a 3-day field alert report directly to CVM as a ''courtesy copy,'' the applicant will be required to submit the ''courtesy copy'' of the report to CVM electronically.

C. Legal Authority

Our legal authority to require electronic submission of postmarketing safety reports for approved new animal drugs derives from sections 201, 301, 501, 502, 512, and 701 of the FD&C Act (21 U.S.C. 321, 331, 351, 352, 360b, and 371).

D. Costs and Benefits

The quantifiable benefit of this rule is annual cost savings of $7,908 from reduced data entry time for CVM. The other benefits of this final rule would be to animal health and are not quantifiable. The main cost of this rule is a one-time upfront cost to industry of $73,500 for changing standard operating procedures (SOPs) and training employees to electronically submit postmarketing safety reports in accordance with the new SOPs. Recurring costs to the Agency would be $161 per year, for processing the waivers to the electronic reporting requirement. Annualizing these costs over a 15-year time horizon (from 2018 to 2033), we estimate total annualized costs to be $6,139 at a 3 percent discount rate, and total annualized costs of $7,703 at a 7 percent discount rate. The annualized net benefit of this rule is −$880 at a 3 percent discount rate and −$2,444 at a 7 percent discount rate. The present value of the net benefits is −$10,504 at a 3 percent discount rate and −$22,262 at a 7 percent discount rate over a 15-year time horizon.

II. Background

A. Need for the Regulation

When a new animal drug is approved and enters the market, the product is introduced to a larger population in settings different from the controlled studies required by the approval process. New information generated during the postmarketing period offers further insight into the benefits and/or risks of the product, and evaluation of this information is important to ensure the safe and effective use of these products.

CVM receives information regarding adverse drug experiences for approved new animal drugs from postmarketing safety reports. For over 25 years, we have received these safety reports on paper. However, the majority of submitters have chosen, voluntarily, to utilize electronic submission as electronic means became available.

In the **Federal Register** of February 14, 2018 (83 FR 6480), we proposed to amend our existing animal drug records and reports regulation in part 514 to require electronic submission of certain postmarketing safety reports for approved new animal drugs and provide a procedure for requesting a temporary waiver of the requirement (83 FR 6480 at 6484). We set forth the rationale that electronic submission improves our ability to process and archive postmarketing safety reports in a timely manner, and to make postmarketing reports more readily available for analysis (83 FR 6480 at 6482).

Electronic submission of postmarketing safety reports:

- Expedites our access to safety information and provides us data in a format that will support more efficient and comprehensive reviews;
- Enhances our ability to rapidly communicate information about suspected problems to animal owners, veterinarians, consumers, and industry within the United States and internationally in support of our public health mission; and
- Eliminates or reduces the time and costs to industry associated with submitting paper reports, and the time, costs, errors, and physical storage needs of the Agency associated with manually entering data from paper reports into the electronic system for review and analysis.

Electronic submission of postmarketing safety reports allows us to be more responsive to rapidly occurring changes in the technological environment. Consistent with our current practice for voluntarily provided electronic submissions, the final rule requires that data in electronic submissions conform to the data elements in Form FDA 1932 and our technical documents on how to provide electronic submissions (*e.g.,* method of transmission and processing, media, file formats, preparation and organization of files). The final rule allows us to issue updated technical documents, as necessary. The most current information on submitting postmarketing safety reports to us in electronic format can be found on our web page at *https://www.fda.gov/animal-veterinary/report-problem/veterinary-adverse-event-reporting-manufacturers* (see, *e.g.,* ''Instructions for Electronic Submission of Mandatory Adverse Event Reports to FDA CVM''). As necessary, we will revise the technical specifications referenced in our technical documents to address changing technical specifications or any additional specifications needed for electronic submission. Using guidance documents and technical documents to communicate these technical specifications will permit us to be more responsive to rapidly occurring changes in the technological environment.

The final rule is also an important step in our continuing efforts to harmonize our postmarketing safety reporting regulations with international standards for submitting safety information. Currently, the technical specifications referenced in our guidance documents supporting the voluntary electronic submission processes rely upon and adopt certain safety reporting and transmission standards recommended by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). VICH was formed to facilitate the harmonization of technical requirements for the marketing authorization or ''registration'' of veterinary medicinal products among three regions: the European Union, Japan, and the United States. Our electronic submission specifications allow applicants or nonapplicants to submit postmarketing safety reports using the Health Level 7 (HL7) Individual Case Safety Report (ICSR) standard that has been adopted worldwide by VICH. In this final rule, we reaffirm our intention to continue to rely on these VICH-recommended standards. We believe the continued use of VICH standards will promote harmonization of safety reporting among regulatory agencies and facilitate the international exchange of postmarketing safety information. Accordingly, this final rule is consistent with our ongoing initiatives to encourage the widest possible use of electronic submission and to promote international harmonization of safety reporting for animal drug products through reliance

on VICH standards. We anticipate that the final rule will enhance industry's global pharmacovigilance practices by allowing it to use common data elements and transmission standards when submitting ICSRs to multiple regulators.

B. Summary of Comments to the Proposed Rule

We received two comment letters on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from industry and an individual. Some comments support our rulemaking and our ongoing efforts to improve our systems for collecting and analyzing postmarketing safety reports. Some comments offer suggestions for specific changes for us to consider making to the subject regulations.

C. General Overview of the Final Rule

This final rule amends our animal drug records and reports regulation at part 514 to require electronic submission of certain postmarketing safety reports for approved new animal drugs. In addition, the rule provides a procedure for requesting a temporary waiver of the requirement. In this rulemaking, we finalize the provisions in the proposed rule.

III. Legal Authority

Our legal authority for issuing this final rule is provided by section 512(*l*) of the FD&C Act relating to records and reports concerning approved new animal drugs and section 701(a) of the FD&C Act. Section 512(*l*) of the FD&C Act requires that, following approval of an NADA or ANADA, applicants must establish and maintain records and make reports to the Agency of data related to experience, as prescribed by regulation or order. FDA has general rulemaking authority under section 701(a) of the FD&C Act, which permits the Secretary of Health and Human Services to promulgate regulations for the efficient enforcement of the FD&C Act. To implement section 512(*l*) of the FD&C Act, FDA promulgated regulations for records and updates concerning experience with new animal drugs (see § 514.80). The final rule's amendments to this regulation will further efficient enforcement of section 512(*l*) by permitting records and reports to be reported electronically.

IV. Comments on the Proposed Rule and FDA Response

A. Introduction

This section summarizes comments we received in response to the proposed rule and our response to those comments. Both commenters support our rulemaking and our ongoing efforts to improve our systems for collecting and analyzing postmarketing safety reports. Some of the comments offer suggestions for additional changes to the subject regulations. We considered the comments we received in response to the proposed rule in preparing this final rule. After considering these comments, we are not making any changes to the codified language that was included in the proposed rule.

In sections IV.B. through IV.C., we describe the comments received on the proposed rule and provide our responses. To make it easier to identify the comments and our responses, the word ''Comment,'' in parentheses, appears before the comment's description, and the word ''Response,'' in parentheses, appears before our response. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Description of General Comments and FDA Response

Two comments make general remarks supporting the proposed rule without focusing on a particular proposed provision.

(Comment 1) Comments generally support our efforts to require electronic submission of certain postmarketing safety reports for approved new animal drugs. One comment recognizes that the requirement of electronic submission would greatly benefit the Agency and animal health by supporting quicker access to postmarketing safety information. Another comment applauds our efforts to improve our systems for collecting and analyzing postmarketing safety reports and to facilitate international harmonization and exchange of safety information.

(Response 1) We appreciate the general support that the comments express. As noted in section II.A., we expect this rule to expedite our access to safety information and provide us data in a format that will support more efficient and comprehensive reviews. This will enhance our ability to rapidly communicate information about suspected problems to animal owners, veterinarians, consumers, and industry within the United States and internationally in support of our public health mission.

C. Specific Comments and FDA Response

Several comments make specific remarks regarding particular proposed provisions. In this section, we discuss and respond to such comments.

(Comment 2) One comment states that, although in favor of electronically reporting 3-day alerts to CVM in addition to reporting to the appropriate FDA District Office or local resident post, until such time that this can be accomplished via a single mechanism (*i.e.,* electronic reporting to both segments of the Agency simultaneously), this places an undue burden on industry both in time and resources as this would require reporting electronically to CVM while continuing to file paper Form FDA 1932 to District Offices or local resident posts.

(Response 2) We currently require 3-day alert reports to be submitted to the appropriate FDA District Office or local FDA resident post on paper (see § 514.80(b)(1)). However, if in addition to that report an applicant elects to submit a 3-day field alert report directly to CVM (*i.e.,* a ''courtesy copy''), we proposed to require the applicant to submit that additional copy of the report to CVM electronically (see proposed § 514.80(b)(1)). At this time FDA District Offices do not have the technology to receive Form FDA 1932 electronically, so we cannot mandate electronic reporting to FDA District Offices at this time. In addition, the FDA District Offices and local FDA resident posts use a different database for tracking such reports, and do not have direct access to the CVM Adverse Drug Event (ADE) database (which receives ADE information in part from Form FDA 1932). We agree that development of a single mechanism to report 3-day alert reports via electronic Form FDA 1932 to both the FDA District Office (or local FDA resident post) and CVM is ideal, and we are interested in developing this capacity; however, this effort is preliminary and investigatory at this time. As there is currently no requirement to provide a ''courtesy copy'' of 3-day alert reports to CVM, the required electronic submission of such copies would only burden those applicants that choose to provide them despite any additional time and resources needed to do so. Therefore, in this final rule, we are keeping the language of the final rule as proposed at

§ 514.80(b)(1). CVM will continue to collaborate with the FDA District Office or local resident post to followup as appropriate in response to 3-day field alert reports submitted directly to the FDA District Office or local resident post.

(Comment 3) One comment notes that, since the implementation of electronic reporting capability, postmarketing safety reports may be submitted to us via Extensible Markup Language (XML), which is designed to store and transport data and be both human-readable and machine-readable. Therefore, there is no official Form FDA 1932 version of these reports to provide to an inspector during manufacturing site FDA inspections. In addition, the comment continues, inspectors are not well versed in reading the XML formats created from electronically submitted reports. The comment suggests that we provide training to inspectors to help them better understand how to read the XML format for case data or that we provide industry with guidance for an alternative form that could be generated from the database that satisfies the inspectors' needs during site inspections.

(Response 3) We recognize the comment's concerns with regard to utility of the XML format information during inspections. We appreciate the commenter's interest in either preparing more easily readable versions of electronically submitted reports for inspectors or providing training to inspectors in reading the XML format of electronically submitted reports. We intend to consider these suggestions so that inspectors are better able to access the information they need during an inspection. However, the comment did not request any changes to the language in proposed § 514.80(b)(1), nor do we see a reason to make any changes based on the concerns and suggestions included in the comment.

(Comment 4) One comment notes that, while the proposed rule provides a procedure for requesting a temporary waiver of the electronic submission requirement for ''good cause'' (*i.e.,* crisis situations that impact an applicant's or nonapplicant's ability to report electronically, such as natural disasters, pandemics, and terrorism), the proposed rule does not change the content, frequency, or timeline for submission of the postmarketing safety reports to the Agency. The comment suggests that, when the Agency's Electronic Submission Gateway or Safety Reporting Portal is down, we should grant a temporary waiver of the electronic submission requirement for the amount of time the Agency website or portal is down.

(Response 4) We disagree that the Agency should automatically grant a temporary waiver from the electronic submission requirement for the amount of time that the Agency's Electronic Submission Gateway or Safety Reporting Portal is down. As stated in the proposed rule, electronic submission improves our ability to process and archive postmarketing safety reports in a timely manner, and to make postmarketing reports more readily available for analysis (83 FR 6480 at 6482). We also stated in the proposed rule that an applicant or nonapplicant experiencing technical difficulty that temporarily prevents use of the Electronic Submission Gateway could, as a backup, electronically submit reports using the Safety Reporting Portal. An applicant or nonapplicant that relies on the Safety Reporting Portal but experiences a short-term, temporary interruption of internet services could, as a backup, electronically submit reports from any other computer with access to a working internet connection (83 FR 6480 at 6485). It is highly unlikely that both the Agency's Electronic Submission Gateway or Safety Reporting Portal would be down at the same time. In the unlikely event that the Agency experiences a prolonged system outage or other major technical problem (which would include the highly unlikely situation where both the Agency's Electronic Submission Gateway or Safety Reporting Portal are down), the Agency does not intend to enforce the requirement to submit reports electronically so long as an applicant or nonapplicant submits reports in an alternate format (most likely on paper using Form FDA 1932).

We are not waiving the required content, frequency, or timeline for submission of the postmarketing safety reports to the Agency, and are finalizing proposed § 514.80(d) without change. The rule requires applicants and nonapplicants to submit a waiver request to us in writing. The initial request for a waiver may be by telephone or email to CVM's Division of Veterinary Product Safety, with prompt written followup submitted as a letter to the application(s). Applicants and nonapplicants should be prepared to comply with an Agency request for submission in an alternate format by maintaining the capability to submit paper reports using Form FDA 1932, if needed.

In addition to the comments specific to this rulemaking that we addressed previously in this preamble, we received general comments expressing views about matters that are not related to this rulemaking. Therefore, these general comments do not require a response.

V. Effective and Compliance Dates

This rule is effective August 28, 2020. Applicants and nonapplicants must comply with the electronic submission requirement in the final rule when submitting their reports beginning on July 29, 2021.

VI. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This final rule is not an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the costs of the rule are minimal in both absolute value and in comparison to average yearly sales of small firms in this industry, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $156 million, using the most current (2019) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

Currently, most submitters have chosen, voluntarily, to use electronic submission for the reports that would be affected by this final rule. As of 2016, 99.7 percent of postmarketing safety reports eligible for electronic submission were electronically submitted. Thus, this final rule would affect a small proportion of these reports.

The quantifiable benefit of this rule is annual cost savings of $5,259 from reduced data entry time for CVM. The other benefits of this final rule would be to animal health and are not quantifiable. The main cost to this rule is a one-time upfront cost to industry of $73,500 for changing SOPs and training employees to electronically submit postmarketing safety reports in accordance with the new SOPs. Recurring costs to the Agency would be $161 per year, for processing the waivers to the electronic reporting requirement. Annualizing these costs over a 15-year time horizon (from 2018 to 2033), we estimate total annualized costs to be $6,139 at a 3 percent discount rate, and total annualized costs of $7,703 at a 7 percent discount rate. The annualized net benefit of this rule is −$880 at a 3 percent discount rate and −$2,444 at a 7 percent discount rate. The present value of the net benefits is −$10,504 at a 3 percent discount rate and −$22,262 at a 7 percent discount rate over a 15-year time horizon.

TABLE 1—SUMMARY OF BENEFITS AND COSTS IN 2017 DOLLARS OVER A 15-YEAR TIME HORIZON

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized	$5,259			2017	7	15	
Monetized $/year	5,259			2017	3	15	
Annualized					7		
Quantified					3		
Qualitative							
Costs:							
Annualized	7,703			2017	7	15	
Monetized $/year	6,139			2017	3	15	
Annualized					7		
Quantified					3		
Qualitative							
Transfers:							
Federal					7		
Annualized Monetized $/year					3		
From/To	From:			To:			
Other					7		
Annualized Monetized $/year					3		
From/To	From:			To:			
Effects:							
State, Local or Tribal Government:							
Small Business:							
Wages:							
Growth:							

In line with Executive Order 13771, in table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. Based on these cost-savings this final rule would be considered a deregulatory action under Executive Order 13771. Our primary estimate for the present value of the net costs over an infinite time horizon is −$3,837 (or a cost savings of $3,837) at a 7 percent discount rate and −$96,287 at a 3 percent discount rate in 2016 dollars.

TABLE 2—EXECUTIVE ORDER 13771 SUMMARY TABLE

[In 2016 dollars over an infinite time horizon]

	Primary (7%)	Lower bound (7%)	Upper bound (7%)	Primary (3%)	Lower bound (3%)	Upper bound (3%)
Present Value of Costs	$69,720			$75,346		
Present Value of Cost Savings	110,711			258,326		
Present Value of Net Costs	(40,991)			(182,980)		
Annualized Costs	4,880			2,260		
Annualized Cost Savings	7,750			7,750		
Annualized Net Costs	(2,869)			(5,489)		

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the one-time and recurring reporting and recordkeeping burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Records and Reports Concerning Experience with Approved New Animal Drugs—OMB Control Number 0910–0284—Revision.

Description: This final rule revises the existing information collection requirements in the postmarketing safety reporting regulations for approved new animal drugs to require electronic submission of certain postmarketing safety reports for approved new animal drugs. This rule does not change the content of these postmarketing reports. It only requires that they be submitted in an electronic form. The rule also provides a procedure for requesting a temporary waiver of the requirement.

Description of Respondents: Respondents to the information collection provisions of this rule are applicants and nonapplicants.

Reporting: Currently, the postmarketing safety reporting regulations for approved new animal drugs include requirements to submit to us postmarketing safety reports of adverse drug experiences and product/manufacturing defects. Section 514.80 requires applicants and nonapplicants to keep records of and report to us data, studies, and other information concerning experience with new animal drugs for each approved NADA and ANADA. Following complaints from animal owners or veterinarians, or following their own detection of a problem, applicants or nonapplicants are required to submit adverse event reports and product/manufacturing defect reports under § 514.80(b)(1) through (3) and (b)(4)(iv)(A) and (C) on Form FDA 1932. Form FDA 1932 may be submitted on paper or electronically via the Electronic Submission Gateway or Safety Reporting Portal. Form FDA 1932a (the voluntary reporting form) is used by veterinarians and the public to submit adverse event reports, product defects, and lack of effectiveness complaints directly to FDA. Form FDA 1932a may be submitted on paper or may be submitted electronically by completing and emailing a fillable PDF form. Form FDA 2301 is used to submit the required transmittal of periodic reports (§ 514.80(b)(4)); special drug experience reports (§ 514.80(b)(5)(i)); promotional material for new animal drugs (§ 514.80(b)(5)(ii)); and distributor statements (§ 514.80(b)(5)(iii)). Form FDA 2301 may be submitted on paper, may be submitted electronically by completing and emailing a fillable PDF form, or may be submitted electronically via CVM's eSubmitter. We review the records and reports required in § 514.80 and the voluntary reports to facilitate a determination under section 512(e) of the FD&C Act as to whether there may be grounds for suspending or withdrawing approval of the new animal drug.

The final rule revises these requirements to require electronic submission of the following postmarketing safety reports for approved new animal drugs:

- Three-day alert reports that applicants elect to submit directly to CVM as a ''courtesy copy'' in addition to the requirement that they have to submit these reports on paper Form FDA 1932 to the appropriate FDA District Office or local FDA resident post (§ 514.80(b)(1));
- Fifteen-day alert reports (§ 514.80(b)(2)(i)) and followup reports (§ 514.80(b)(2)(ii));
- Product/manufacturing defects and adverse drug experience reports submitted by nonapplicants who elect to report adverse drug experiences directly to FDA under § 514.80(b)(3) in addition to providing these reports to the applicant; and
- Product/manufacturing defects and adverse drug experience reports (including reports of previously not reported adverse drug experiences that occur in postapproval studies) required to be submitted as part of the periodic drug experience report (§ 514.80(b)(4)(iv)(A) and (C)).

We currently require 3-day alert reports to be submitted to the appropriate FDA District Office or local FDA resident post on paper (see § 514.80(b)(1)). As noted previously, the regulation does not require electronic submission of 3-day field alert reports (§ 514.80(b)(1)). These reports will continue to be submitted on paper Form FDA 1932 directly to the appropriate FDA District Office or local resident post. However, as noted, if an applicant elects to submit a 3-day field alert report directly to CVM as a ''courtesy copy,'' the applicant will be required to submit the report electronically. This will not alleviate the applicant's responsibility to submit this report to the FDA District Field Office or local FDA resident post on paper Form FDA 1932.

The final rule also revises these requirements to allow applicants or nonapplicants to request a temporary waiver from the electronic submission requirement for ''good cause'' shown. We anticipate that temporary waivers will only be needed in rare circumstances that impact an applicant's or nonapplicant's ability to report electronically, such as natural disasters, pandemics, and terrorism.

In the February 14, 2018, proposed rule, we included an analysis of the information collection provisions of the proposal under the PRA and requested comments on four topics relevant to that analysis (83 FR 6480 at 6487 through 6488). We have summarized and responded to these comments in sections IV.B. through IV.C., but have made no changes to the burden estimate in our proposed rule.

We estimate the reporting burden of this collection of information as follows:

TABLE 3—ESTIMATED RECURRING REPORTING BURDEN [1]

21 CFR section	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic submission of postmarketing safety reports under § 514.80(b)(1), (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) and (C)	1932	15	18	270	1	270
Request for waiver, § 514.80(d)(2)	N/A	1	1	1	1	1
Total				271		271

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 3 shows the estimated recurring reporting burden associated with the final rule. In section II.F. of the Final Regulatory Impact Analysis (FRIA), we estimated that 15 firms submitted a paper Form FDA 1932 report from 2011 to 2015 and thus will be affected by the rule's requirement to submit electronically. As stated in the FRIA, we estimate that in 2016 CVM received 270 of the affected postmarketing safety reports on paper. We calculate the number of responses per respondent as the total annual responses divided by the number of respondents. We estimate that, on average, it will take 1 hour to submit electronic postmarketing safety reports for approved new animal drugs, for a total of 270 hours. We base our estimate of 1 hour per report on our experience with electronic postmarketing safety reporting. In the FRIA, we also estimated the burdens associated with submission of waiver requests. We expect very few waiver requests (see section II.F.2. of the FRIA), estimating that one firm will request a waiver annually under § 514.80(d)(2). We assume a waiver request takes 1 hour to prepare and submit to us. Together, this results in a total of 271 hours and 271 responses. We are also adding 1 hour to the paper reporting collection to reflect the new waiver request process under § 514.80(d)(2).

We estimate the recordkeeping burden of this collection of information as follows:

TABLE 4—ESTIMATED ONE-TIME RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Write New SOPs	15	1	15	20	300
Training	15	1	15	20	300
Total			30		600

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 4 shows the estimated one-time recordkeeping burden associated with the final rule. This burden includes both the one-time burden of creating new SOPs to submit the reports electronically and the one-time cost of training employees to electronically submit postmarketing safety reports to CVM in accordance with the new SOPs. In section II.F. of the FRIA, we estimated that approximately 15 firms will be affected by this rule. We assume it will take an average of 20 hours per firm to create new SOPs for electronic submission of postmarketing safety reports and approximately 20 hours per firm to complete the training of employees to electronically submit postmarketing safety reports in accordance with the new SOPs. Together, this results in a total of 600 hours and 30 records. We assume that there are no capital costs associated with firms implementing this rule (*i.e.,* applicants and nonapplicants in the pharmaceutical industry already have the computer and internet capacity necessary to electronically submit postmarketing safety reports).

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive order and, consequently, a

tribal summary impact statement is not required.

XI. References

1. Economic Analysis of Impacts; also available at: *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.

List of Subjects in 21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 514 is amended as follows:

PART 514—NEW ANIMAL DRUG APPLICATIONS

■ 1. The authority citation for part 514 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 354, 356a, 360b, 360ccc, 371, 379e, 381.

■ 2. Section 514.80 is amended as follows:

■ a. Revise the entries in the table for paragraphs (b)(4), (d), (e), and (g);

■ b. Add a fifth sentence to paragraph (b)(1); and

■ c. Revise the last sentence of paragraph (b)(2)(i); the third sentence of paragraph (b)(2)(ii); the last sentence of paragraph (b)(3); paragraphs (b)(4)(iv)(A) and (C); the fifth sentence of paragraph (b)(4)(v); and paragraphs (d) and (g).

The addition and revisions read as follows:

§ 514.80 Records and reports concerning experience with approved new animal drugs.

* * * * *

Purpose	21 CFR paragraph and title
* * * * *	* *
What are the general requirements for submission of periodic drug experience reports, *e.g.,* method of submission, submission date and frequency, when is it to be submitted, how many copies?.	514.80(b)(4) Periodic drug experience report.
How do I petition to change the date of submission or frequency of submissions?	
* * * * *	* *
What reports must be submitted to FDA electronically?	514.80(d) Format for Submissions.
How can I apply for a waiver from the electronic reporting requirements?	
How do I obtain Form FDA 1932 and Form FDA 2301?	
How long must I maintain records and reports required by this section?	514.80(e) Records to be maintained.
* * * * *	* *
Where do I mail reports that are not required to be submitted electronically?	514.80(g) Mailing addresses.
* * * * *	* *

* * * * *

(b) * * *

(1) * * * If the applicant elects to also report directly to the FDA's Center for Veterinary Medicine (CVM), the applicant must submit the report to CVM in electronic format as described in paragraph (d)(1) of this section, unless the applicant obtains a waiver under paragraph (d)(2) of this section or FDA requests the report in an alternate format.

(2) * * *

(i) * * * The report must be submitted to FDA in electronic format as described in paragraph (d)(1) of this section, unless the applicant obtains a waiver under paragraph (d)(2) of this section or FDA requests the report in an alternate format.

(ii) * * * A followup report must be submitted to FDA in electronic format as described in paragraph (d)(1) of this section, unless the applicant obtains a waiver under paragraph (d)(2) of this section or FDA requests the report in an alternate format. * * *

(3) * * * If the nonapplicant elects to also report directly to FDA, the nonapplicant must submit the report to FDA in electronic format as described in paragraph (d)(1) of this section, unless the nonapplicant obtains a waiver under paragraph (d)(2) of this section or FDA requests the report in an alternate format.

(4) * * *

(iv) * * *

(A) Product/manufacturing defects and adverse drug experiences not previously reported under paragraphs (b)(1) and (2) of this section must be reported individually to FDA in electronic format as described in paragraph (d)(1) of this section, unless the applicant obtains a waiver under paragraph (d)(2) of this section or FDA requests the report in an alternate format.

* * * * *

(C) Reports of previously not reported adverse drug experiences that occur in postapproval studies must be reported individually to FDA in electronic format as described in paragraph (d)(1) of this section, unless the applicant obtains a waiver under paragraph (d)(2) of this section or FDA requests the report in an alternate format.

(v) * * * The summaries must state the time period on which the increased frequency is based, time period comparisons in determining increased frequency, references to any reports previously submitted under paragraphs (b)(1), (2), and (3) and (b)(4)(iv)(A) and (C) of this section, the method of analysis, and the interpretation of the results. * * *

* * * * *

(d) *Format for submissions*—(1) *Electronic submissions.* Except as provided in paragraph (d)(2) of this section, reports submitted to FDA under paragraphs (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) and (C) of this section and reports submitted to CVM under paragraph (b)(1) of this section must be submitted in an electronic format that FDA can process, review, and archive. Data provided in electronic submissions must be in conformance with the data elements in Form FDA 1932 and FDA technical documents describing transmission. As necessary, FDA will issue updated technical documents on how to provide the electronic submission (*e.g.,* method of transmission and processing, media, file formats, preparation, and organization of files). Unless requested by FDA, paper copies of reports submitted electronically should not be submitted to FDA.

(2) *Waivers.* An applicant or nonapplicant may request, in writing, a temporary waiver of the electronic

submission requirements in paragraph (d)(1) of this section. The initial request may be by telephone or email to CVM's Division of Veterinary Product Safety, with prompt written followup submitted as a letter to the application(s). FDA will grant waivers on a limited basis for good cause shown. If FDA grants a waiver, the applicant or nonapplicant must comply with the conditions for reporting specified by FDA upon granting the waiver.

(3) *Paper forms.* If approved by FDA before use, a computer-generated equivalent of Form FDA 1932 may be used for reports submitted to the appropriate FDA District Office or local FDA resident post under paragraph (b)(1) of this section and to FDA under paragraph (d)(2) of this section, and a computer-generated equivalent of Form FDA 2301 may be used for reports submitted to FDA under paragraph (b)(4) of this section. Form FDA 1932 may be obtained on the FDA website, by telephoning CVM's Division of Veterinary Product Safety, or by submitting a written request to the following address: Food and Drug Administration, Center for Veterinary Medicine, Division of Veterinary Product Safety (HFV–240), 7500 Standish Pl., Rockville, MD 20855–2764. Form FDA 2301 may be obtained on the FDA website, by telephoning CVM's Division of Surveillance (HFV–210), or by submitting a written request to the following address: Food and Drug Administration, Center for Veterinary Medicine, Division of Surveillance (HFV–210), 7500 Standish Pl., Rockville, MD 20855–2764.

* * * * *

(g) *Mailing addresses.* Three-day alert reports must be submitted to the appropriate FDA District Office or local FDA resident post. Addresses for District Offices and resident posts may be obtained on the FDA website. Other reports not required to be submitted to FDA in electronic format must be submitted to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855–2764.

* * * * *

Dated: July 2, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

[FR Doc. 2020–15441 Filed 7–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 120

[Public Notice: 11157]

International Traffic in Arms Regulations: Notification of Temporary Suspension, Modification, or Exception to Regulations

AGENCY: Department of State.

ACTION: Extension of temporary suspensions, modifications, and exceptions.

SUMMARY: The Department of State is issuing this document to inform the public of an extension to certain temporary suspensions, modifications, and exceptions for the durations described herein to certain provisions of the International Traffic in Arms Regulations (ITAR) in order to provide for continued telework operations during the current SARS–COV2 public health emergency. These actions are taken in order to ensure continuity of operations within the Directorate of Defense Trade Controls (DDTC) and among members of the regulated community.

DATES: This document is issued July 29, 2020.

FOR FURTHER INFORMATION CONTACT: Sarah Heidema, Office of Defense Trade Controls Policy, U.S. Department of State, telephone (202) 663–1282, or email *DDTCResponseTeam@state.gov.* ATTN: Extension of Suspension, Modification, and Exception.

SUPPLEMENTARY INFORMATION: On May 1, 2020, the Directorate of Defense Trade Controls (DDTC) published in the **Federal Register** a notification of certain temporary suspensions, modifications, and exceptions to the ITAR, necessary in order to ensure continuity of operations within DDTC and among entities registered with DDTC pursuant to part 122 of the ITAR (85 FR 25287). These actions were taken pursuant to ITAR § 126.2, which allows for the temporary suspension or modification of provisions of the ITAR, and ITAR § 126.3, which allows for exceptions to provisions of the ITAR. These actions were taken in the interest of the security and foreign policy of the United States and warranted as a result of the exceptional and undue hardships and risks to safety caused by the public health emergency related to the SARS–COV2 pandemic. The President declared a national emergency on March 13, 2020, as a result of this public health crisis.[1]

Subsequently, on June 10, 2020 (85 FR 35376), DDTC published in the **Federal Register** a request for comment from the regulated community regarding the efficacy and termination dates of the temporary suspensions, modifications, and exceptions provided in 85 FR 25287, and requesting comment as to whether additional measures should be considered in response to the public health crisis. DDTC received comments from several individual entities and from an industry association. DDTC appreciates the efforts expended by those commenters and took all comments under consideration. In the interest of providing this notice as expeditiously as possible, DDTC will not address each of the comments in turn, but will provide this abridged response. Of the four temporary suspensions, modifications, and exceptions to the ITAR announced in the May 1 notice referenced above, DDTC is allowing number 1 (extension of registrations) and number 2 (duration of ITAR licenses and agreements) to terminate in accordance with the timelines provided therein. The remaining two temporary suspensions, modifications, and exceptions, number 3 (§ 120.39(a)(2) allowance for remote work) and number 4 (authorization to allow remote work under technical assistance agreement, manufacturing agreement, or exemption) are extended and shall terminate on December 31, 2020.

The majority of the commenters requested that the telework provisions (numbers 3 and 4) be extended and DDTC agrees. Based upon continued public health recommendations and as informed by responses to request for public comment, it is apparent to DDTC that regulated entities will continue to engage in social distancing measures for the foreseeable future. In order to accommodate teleworking and decentralized workplaces, several commenters recommended extending these temporary modifications through at least the end of October or this calendar year. DDTC is extending the temporary modifications through the end of the calendar year in order to provide regulated entities with staffing flexibilities in the immediate term. DDTC will use this period to fully investigate the possibility and ramifications of making this modification, or a variation thereof, a permanent revision to the ITAR. If necessary, this extension will provide an opportunity to utilize notice and comment rulemaking and to address potential revisions through the interagency process. An extension of

[1] Proclamation 9994 of March 13, 2020, 85 FR 15337 (Mar. 18, 2020).

this length also will provide an extended operational window for regulated entities during the course of the public health crisis. DDTC believes that a failure to extend these temporary suspensions, modifications, and exceptions will have a negative impact on regulated entities' ability to safely engage in continued operations. As persons and entities subject to the regulations or operating pursuant to a license or other approval are located around the world, it is apparent that physical presence may contradict public health guidance or legal requirements in many instances. For these reasons, DDTC is extending the termination date prescribed in 85 FR 25287, items number 3 and number 4.

The temporary suspension, modification, and exception to the requirement in ITAR parts 122 and 129 to renew registration as a manufacturer, exporter, and/or broker and pay a fee on an annual basis described at number 1 of 85 FR 25287, is not being extended to subsequent registrations. DDTC did not receive any request from industry for additional extensions to registrations that terminate after June 30. To the contrary, several commenters expressed their appreciation for the original action, but noted that any extension would be unnecessary. DDTC's experience since the original temporary suspension, modification, and exception is that registrants are able to use DDTC's DECCS online system for the purpose of registration in the normal course of business.

The temporary suspension, modification, and exception to the limitations on the duration of ITAR licenses and agreements described at number 2 of 85 FR 25287, is not extended. Although several commenters expressed appreciation for the original action, one commenter indicated a preference that it not be extended. Although three commenters did request extension for various reasons, DDTC is not accepting those requests. DDTC notes that the majority of commenters did not make such a request, and that of those that did, some of the reasons related to internal DDTC operations and coordination with other areas of the government. DDTC believes that progress is being made on those matters and that continued extensions to all existing authorizations is an overbroad response to the current situation. DDTC, its interagency partners, and the regulated entities have had several months to adjust to the current situation and DDTC believes it is prepared to handle authorizations in accordance with its statutory requirements.

DDTC further notes that several commenters requested additional measures be taken by DDTC. DDTC is not adopting any of those measures at this time. Although DDTC is not providing individual responses to those requests, DDTC notes generally that several of the requests would involve major infrastructure revisions to DDTC automated systems and are therefore not feasible as temporary suspensions, modifications, or exceptions; others were outside the scope of the request; and others involved matters of internal policy and practice and not regulatory matters. For all regulatory matters recommended, DDTC will continue to consider those that may merit future possibility of action.

Therefore, pursuant to ITAR §§ 126.2 and 126.3, in the interest of the security and foreign policy of the United States and as warranted by the exceptional and undue hardships and risks to safety caused by the public health emergency related to the SARS–COV2 pandemic, notice is provided that the following temporary suspensions, modifications, and exceptions are being extended as follows:

1. As of March 13, 2020, a temporary suspension, modification, and exception to the requirement that a regular employee, for purposes of ITAR § 120.39(a)(2), work at the company's facilities, to allow the individual to work at a remote work location, so long as the individual is not located in Russia or a country listed in ITAR § 126.1. This suspension, modification, and exception shall terminate on December 31, 2020, unless otherwise extended in writing.

2. As of March 13, 2020, a temporary suspension, modification, and exception to authorize regular employees of licensed entities who are working remotely in a country not currently authorized by a technical assistance agreement, manufacturing license agreement, or exemption to send, receive, or access any technical data authorized for export, reexport, or retransfer to their employer via a technical assistance agreement, manufacturing license agreement, or exemption so long as the regular employee is not located in Russia or a country listed in ITAR § 126.1. This suspension, modification, and exception shall terminate on December 31, 2020, unless otherwise extended in writing.

This notice makes no other revision to the notice published at 85 FR 25287, nor does it make any other temporary suspension, modification, or exception to the requirements of the ITAR.

Authority: 22 CFR 126.2 and 126.3.

Zachary A. Parker,

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

[FR Doc. 2020–15777 Filed 7–28–20; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[TD 9904]

RIN 1545–BP89

Recapture of Excess Employment Tax Credits Under the Families First Act and the CARES Act

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document amends the regulations under sections 3111 and 3221 of the Internal Revenue Code with the addition of temporary regulations issued under the regulatory authority granted by the Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security Act to prescribe such regulations as may be necessary for reconciling advance payments of refundable employment tax credits provided under these acts and recapturing the benefit of the credits when necessary. Consistent with this authority, these temporary regulations authorize the assessment of any erroneous refund of the credits paid under sections 7001 and 7003 of the Families First Coronavirus Response Act, including any increases in such credits under section 7005 thereof, and section 2301 of the Coronavirus Aid, Relief, and Economic Security Act. The text of these temporary regulations also serves as the text of the proposed regulations (REG–111879–20) set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register**.

DATES:

Effective Date: These temporary regulations are effective on July 29, 2020.

Applicability Date: For date of applicability, *see* §§ 31.3111–6T and 31.3221–5T of these temporary regulations.

FOR FURTHER INFORMATION CONTACT: Concerning these temporary regulations, NaLee Park at 202–317–6798.

SUPPLEMENTARY INFORMATION:

Background

I. The Statutes in General: The Families First Act and the CARES Act

The Families First Coronavirus Response Act (Families First Act), Public Law 116–127, 134 Stat. 178 (2020), enacted on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116–136, 134 Stat. 281 (2020), enacted on March 27, 2020, provide relief to taxpayers from economic hardships resulting from the Coronavirus Disease 2019 (COVID–19).

The Families First Act, through the enactment of the Emergency Paid Sick Leave Act and the Emergency Family and Medical Leave Expansion Act, generally requires employers with fewer than 500 employees to provide paid leave due to certain circumstances related to COVID–19.

Division E of the Families First Act, the Emergency Paid Sick Leave Act (EPSLA), requires certain employers to provide employees with up to 80 hours of paid sick leave if the employee is unable to work or telework because the employee:

(1) Is subject to a Federal, State, or local quarantine or isolation order related to COVID–19;

(2) has been advised by a health care provider to self-quarantine due to concerns related to COVID–19;

(3) is experiencing symptoms of COVID–19 and seeking a medical diagnosis;

(4) is caring for an individual who is subject to a Federal, State, or local quarantine or isolation order related to COVID–19, or has been advised by a health care provider to self-quarantine due to concerns related to COVID–19;

(5) is caring for a son or daughter of such employee if the school or place of care of the son or daughter has been closed, or the child care provider of such son or daughter is unavailable, due to COVID–19 precautions; or

(6) is experiencing any other substantially similar condition specified by the Secretary of Health and Human Services in consultation with the Secretaries of the Treasury and Labor.[1]

An employee who is unable to work or telework for reasons related to COVID–19 described in (1), (2), or (3) above is entitled to paid sick leave at the employee's regular rate of pay or, if higher, the Federal minimum wage or any applicable State or local minimum wage, up to $511 per day and $5,110 in the aggregate. An employee who is unable to work or telework for reasons related to COVID–19 described in (4), (5), or (6) above is entitled to paid sick leave at two-thirds the employee's regular rate of pay or, if higher, the Federal minimum wage or any applicable State or local minimum wage, up to $200 per day and $2,000 in the aggregate.

Division C of the Families First Act, the Emergency Family and Medical Leave Expansion Act (EFMLEA), amends the Family and Medical Leave Act of 1993 to require certain employers to provide expanded paid family and medical leave to employees who are unable to work or telework for reasons related to COVID–19. An employee can receive up to 10 weeks of paid family and medical leave at two-thirds the employee's regular rate of pay, up to $200 per day and $10,000 in the aggregate if the employee is unable to work or telework because the employee is caring for a son or daughter whose school or place of care is closed or whose child care provider is unavailable for reasons related to COVID–19.

Sections 7001 and 7003 of the Families First Act generally provide that employers subject to the paid leave requirements under EPSLA and EFMLEA (''eligible employers'') are entitled to fully refundable tax credits to cover the cost of the leave required to be paid for those periods of time during which employees are unable to work or telework for reasons related to COVID–19.[2]

Eligible employers are entitled to receive a refundable credit equal to the amount of the qualified sick leave wages and qualified family leave wages (collectively ''qualified leave wages''), plus allocable qualified health plan expenses. Under the respective provisions, qualified leave wages are defined to mean wages (as defined in section 3121(a) of the Internal Revenue Code (Code)) and compensation (as defined in section 3231(e) of the Code) paid by an employer which are required to be paid under the EPSLA and EFMLEA. See section 7001(c) and 7003(c). The credit is allowed against the taxes imposed on employers by section 3111(a) of the Code (the Old-Age, Survivors, and Disability Insurance tax (social security tax)), first reduced by any credits claimed under sections 3111(e) and (f) of the Code, and section 3221(a) of the Code (the Railroad Retirement Tax Act Tier 1 tax), on all wages and compensation paid to all employees. Under section 7005 of the Families First Act, the qualified leave wages are not subject to the taxes imposed on employers by sections 3111(a) and 3221(a) of the Code. In addition, section 7005 provides that the credits under sections 7001 and 7003 of the Families First Act are increased by the amount of the tax imposed by section 3111(b) of the Code (employer's share of Medicare tax) on qualified leave wages.[3]

The CARES Act provides an additional credit for employers experiencing economic hardship related to COVID–19. Under section 2301 of the CARES Act, certain employers who pay qualified wages to their employees are eligible for an employee retention credit. Employers eligible for the employee retention credit are employers that carry on a trade or business during calendar year 2020 and tax-exempt organizations that either have a full or partial suspension of operations during any calendar quarter in 2020 due to an order from an appropriate governmental authority limiting commerce, travel, or group meetings (for commercial, social, religious, or other purposes) due to COVID–19, or experience a significant decline in gross receipts during the calendar quarter.

Qualified wages are wages (as defined in section 3121(a) of the Code) and compensation (as defined in section 3231(e) of the Code) paid by an employer to some or all employees after March 12, 2020, and before January 1, 2021, and include the employer's qualified health plan expenses that are properly allocable to such wages or compensation. For employers that averaged more than 100 full-time employees during 2019, qualified wages are wages and compensation (including allocable qualified health plan expenses), up to $10,000 per employee, paid to employees that are not providing services because operations were fully or partially suspended due to orders from an appropriate governmental authority or due to a decline in gross receipts. For employers who averaged 100 full-time employees or fewer during 2019, qualified wages are wages and compensation (including allocable qualified health plan expenses), up to $10,000 per employee, paid to any employee during the period operations were suspended due to orders from an

[1] The U.S. Department of Health and Human Services has not yet specified any other such conditions as of July 29, 2020.

[2] Under sections 7001(d)(4) and 7003(d)(4) of the Families First Act, these credits do not apply to the government of the United States, the government of any State or political subdivision thereof, or any agency or instrumentality of any of the foregoing.

[3] The credit for the employer's share of Medicare tax does not apply to eligible employers that are subject to Railroad Retirement Tax Act (RRTA) because under section 7005(a) of the Families First Act qualified leave wages are not subject to Medicare tax under RRTA due to that section's reference to section 3221(a) of the Code, which includes both social security tax and Medicare tax.

appropriate governmental authority or due to a decline in gross receipts, regardless of whether its employees are providing services.

The employee retention credit is a fully refundable tax credit for employers equal to 50 percent of qualified wages. Because the maximum amount of qualified wages taken into account with respect to each employee is $10,000, the maximum employee retention credit for an eligible employer for qualified wages paid to any employee is $5,000. The credit is allowed against the taxes imposed on employers by section 3111(a) of the Code, first reduced by any credits allowed under sections 3111(e) and (f) of the Code and sections 7001 and 7003 of the Families First Act, and the taxes imposed under section 3221(a) of the Code that are attributable to the rate in effect under section 3111(a) of the Code, first reduced by any credits allowed under sections 7001 and 7003 of the Families First Act, on all wages and compensation paid to all employees. The same wages or compensation cannot be counted for both the Families First Act leave credits and the CARES Act employee retention credit.

II. Refundability of Credits

Sections 7001(b)(4) and 7003(b)(3) of the Families First Act provide that if the amount of the paid sick and family leave credits under these sections exceeds the taxes imposed by section 3111(a) or 3221(a) of the Code for any calendar quarter, such excess shall be treated as an overpayment that shall be refunded under sections 6402(a) and 6413(b) of the Code. Section 2301(b)(3) of the CARES Act provides that if the amount of the employee retention credit exceeds the taxes imposed by section 3111(a) or 3221(a) (limited to the portion attributable to the rate in effect under section 3111(a)) of the Code for any calendar quarter, such excess shall be treated as an overpayment that shall be refunded under sections 6402(a) and 6413(b) of the Code.

Section 6402(a) of the Code provides that, within the applicable period of limitations, overpayments may be credited against any liability in respect of an internal revenue tax on the part of the person who made the overpayment and any remaining balance refunded to such person. Section 6413(b) provides that if more than the correct amount of employment tax imposed by sections 3101, 3111, 3201, 3221, or 3402 is paid or deducted and the overpayment cannot be adjusted under section 6413(a),[4] the amount of the overpayment shall be refunded (subject to the applicable statute of limitations) as the Secretary may prescribe in regulations.

The IRS has revised Form 941, *Employer's Quarterly Federal Tax Return,* and is revising Form 943, *Employer's Annual Federal Tax Return for Agricultural Employees,* Form 944, *Employer's Annual Federal Tax Return,* and Form CT–1, *Employer's Annual Railroad Retirement Tax Return,* so that employers may use these returns to claim the paid sick and family leave credits under the Families First Act and the employee retention credit under the CARES Act. The revised employment tax returns will provide for any credits in excess of the taxes imposed under sections 3111(a) or 3221(a) (for the employee retention credit, only the taxes imposed under section 3221(a) that are attributable to the rate in effect under section 3111(a)) to be credited against other employment taxes and then for any remaining balance to be refunded to the employer (per section 6402(a) or section 6413(b)).[5]

III. Advance Payment of Credits and Erroneous Refunds

Section 3606 of the CARES Act amends sections 7001(b)(4) and 7003(b)(3) of the Families First Act to provide that, in anticipation of the paid sick and family leave credits under these sections, including any refundable portions (which would include any increases in the credits under section 7005), these credits may be advanced, according to forms and instructions provided by the Secretary, up to the total allowable amount and subject to applicable limits for the calendar quarter. Section 2301(l)(1) of the CARES Act provides that the Secretary shall issue such forms, instructions, regulations, and guidance as are necessary to allow the advance payment of the employee retention credit under section 2301, subject to the limitations provided in section 2301 and based on such information as the Secretary shall require.

To implement the advance payment provisions of the Families First Act and the CARES Act, the IRS has created Form 7200, *Advance Payment of Employer Credits Due To COVID–19,* which employers may use to request an advance of the paid sick or family leave credits under the Families First Act, the employee retention credit under the CARES Act, or two or more of them. Employers are required to reconcile any advance payments claimed on Form 7200 with total credits claimed and total taxes due on their employment tax returns. A refund, a credit, or an advance of any portion of these credits to a taxpayer in excess of the amount to which the taxpayer is entitled is an erroneous refund for which the IRS must seek repayment.

IV. Assessment Authority

Section 6201, in general, authorizes the Secretary to determine and assess tax liabilities including interest, additional amounts, additions to the tax, and assessable penalties. However, the general authority to assess tax liabilities under section 6201(a) does not allow the assessment of any non-rebate[6] portion of an erroneous refund of a refundable credit. Instead, non-rebate refunds are generally recovered or recaptured through voluntary payment or litigation. The government by appropriate action can bring civil litigation to recover funds which its agents have wrongfully, erroneously, or illegally paid, and no statute is necessary to authorize the government to sue in such a case, since the right to sue is independent of statute. *United States* v. *Wurts,* 303 U.S. 414, 415 (1938), citing *United States* v. *The Bank of the Metropolis,* 40 U.S. 377 (1841). However, the statutory language of the Families First Act and the CARES Act provides for the administrative recapture of these non-rebate refunds by authorizing the promulgation of regulations or other guidance to do so.

Sections 7001 and 7003 of the Families First Act and section 2301 of the CARES Act grant authority to the Department of the Treasury (Treasury Department) and the IRS to issue regulations or other guidance to recapture an erroneous refund of the credits. Specifically, sections 7001(f)

[4] Section 6413(a) addresses interest-free adjustments of overpayments. The section provides that if more than the correct amount of employment tax imposed by section 3101, 3111, 3201, 3221, or 3402 is paid with respect to any payment of remuneration, proper adjustments with respect to both the tax and the amount to be deducted, shall be made, without interest, in such manner and at such times as the Secretary may by regulations prescribe.

[5] Employment tax returns have also been revised to provide for reporting of any deferral of employment taxes under the CARES Act. Section 2302 of the CARES Act provides that employers may defer the deposit and payment of the employer's share of social security tax for the payroll tax deferral period of March 27, 2020 through December 31, 2020. The deferral applies in addition to the credits claimed on an employment tax return, but the deferral does not reduce the amount of the employer's share of social security tax against which the credits are applied.

[6] ''Non-rebate'' refers to the portion of any refund of a credit that exceeds the IRS's determination of the recipient's tax liability (*i.e.,* the remaining portion of the refund that is paid to the recipient after the refund has been applied to the recipient's tax liability).

and 7003(f) of the Families First Act and section 2301(l) of the CARES Act authorize the Secretary to issue guidance to allow for the administrative reconciliation and recapture of erroneous refunds. Sections 7001(f) and 7003(f) of the Families First Act provide, in relevant part, that the Secretary (or the Secretary's delegate) shall provide such regulations or other guidance as may be necessary to carry out the purposes of the credit, including regulations or other guidance: (1) To prevent the avoidance of the purposes of the limitations under this provision; (2) to minimize compliance and record-keeping burdens associated with the credit; (3) to provide for a waiver of penalties for failure to deposit amounts in anticipation of the allowance of the credit; (4) to recapture the benefit of the credit in cases where there is a subsequent adjustment to the credit; and (5) to ensure that the wages taken into account for the credit conform with the paid sick leave and paid family leave required to be provided under the Families First Act. Similarly, section 2301(l) of the CARES Act provides in relevant part that the Secretary shall issue such forms, instructions, regulations, and guidance as are necessary to provide for the reconciliation of an advance payment of the employee retention credit with the amount advanced at the time of filing the return of tax for the applicable calendar quarter or taxable year, and to provide for the recapture of the credit under section 2301 of the CARES Act if such credit is allowed to a taxpayer that receives a small business loan under section 1102 of the CARES Act during a subsequent quarter.

Accordingly, this document amends the Employment Tax Regulations (26 CFR part 31) by adding temporary regulations under sections 3111 and 3221 of the Code. Concurrent with the publication of this Treasury decision, the Treasury Department and the IRS are publishing in the Proposed Rules section of this issue of the **Federal Register** a notice of proposed rulemaking (REG–111879–20) on this subject that cross-references the text of these temporary regulations. *See* section 7805(e)(1). Interested persons are directed to the **ADDRESSES** and COMMENTS AND REQUESTS FOR A PUBLIC HEARING sections of the preamble to REG–111879–20 for information on submitting public comments or requesting a public hearing on the proposed regulations.

Explanation of Provisions

Sections 7001 and 7003 of the Families First Act and section 2301 of the CARES Act provide that the credits described in these sections are taken against the taxes imposed on employers under sections 3111(a) or 3221(a) of the Code (for the employee retention credit, only the taxes imposed under section 3221(a) that are attributable to the rate in effect under section 3111(a) of the Code). Additionally, if the amount of the credit exceeds the taxes imposed under sections 3111(a) or 3221(a) of the Code (for the employee retention credit, only the taxes imposed under section 3221(a) that are attributable to the rate in effect under section 3111(a) of the Code) for any calendar quarter, such excess shall be treated as an overpayment to be refunded or credited under sections 6402(a) and 6413(b) of the Code. Any credits claimed that exceed the amount to which the employer is entitled and that are actually credited or paid by the IRS are considered to be erroneous refunds of the credits. These temporary regulations provide that erroneous refunds of these credits are treated as underpayments of the taxes imposed under sections 3111(a) or 3221(a) of the Code and authorize the IRS to assess any portion of the credits erroneously credited, paid, or refunded in excess of the amount allowed as if those amounts were tax liabilities under sections 3111(a) and 3221(a) subject to assessment and administrative collection procedures. This allows the IRS to efficiently recover the amounts, while also preserving administrative protections afforded to taxpayers with respect to contesting their tax liabilities under the Code and avoiding unnecessary costs and burdens associated with litigation. These assessment and administrative collection procedures will apply in the normal course in processing employment tax returns that report advances in excess of claimed credits and in examining returns for excess claimed credits.

Specifically, these temporary regulations provide that any amount of the credits for qualified leave wages under sections 7001 and 7003 of the Families First Act, plus any amount of credits for qualified health plan expenses under sections 7001 and 7003, and including any increases in these credits under section 7005, and any amount of the employee retention credit for qualified wages under section 2301 of the CARES Act that are erroneously refunded or credited to an employer shall be treated as underpayments of the taxes imposed by section 3111(a) or section 3221(a), as applicable, by the employer and may be administratively assessed and collected in the same manner as the taxes. These temporary regulations provide that the determination of any amount of credits erroneously refunded must take into account any credit amounts advanced to an employer under the process established by the IRS in accordance with sections 7001(b)(4)(A)(ii) and 7003(b)(3)(B) of the Families First Act and section 2301(l)(1) of the CARES Act.

Because in certain situations third party payors claim credits on behalf of their common law employer clients, these temporary regulations also provide that employers against whom an erroneous refund of credits can be assessed as an underpayment include persons treated as the employer under sections 3401(d), 3504, and 3511 of the Code, consistent with their liability for the section 3111(a) and section 3221(a) taxes against which the credit applied.

Finally, these temporary regulations apply to all credit refunds under section 7001 and 7003 of the Families First Act advanced or paid on or after April 1, 2020 and all credit refunds under section 2301 of the CARES Act advanced or paid on or after March 13, 2020. These applicability dates correspond to the effective dates of the statutory sections that provide for these credits and that authorize guidance to allow for the administrative reconciliation and recapture of erroneous refunds of these credits.

Sections 7001(g) and 7003(g) of the Families First Act provide that sections 7001 and 7003 apply to wages paid with respect to the period beginning on a date selected by the Secretary of the Treasury which is during the 15-day period beginning on the date of the enactment of the Families First Act (March 18, 2020). In Notice 2020–21, 2020–16 I.R.B. 660, the IRS provided that the tax credits for qualified sick leave wages and qualified family leave wages under sections 7001 and 7003 of the Families First Act apply to wages paid for the period beginning on April 1, 2020, and ending on December 31, 2020. Section 2301(m) of the CARES Act provides that section 2301 applies to wages paid on or after March 13, 2020, and before January 1, 2021.

Pursuant to section 7805(b)(2) of the Code, these temporary regulations are permitted to apply before the dates provided under section 7805(b)(1), including the date on which these temporary regulations are filed with the **Federal Register**, because these temporary regulations are being issued within 18 months of the date of the enactment of the relevant statutory provisions under the Families First Act and the CARES Act. Accordingly, these temporary regulations apply to all

credits under sections 7001 and 7003 of the Families First Act, as modified by section 3606 of the CARES Act, including any increases in the credits under section 7005 of the Families First Act, refunded on or after April 1, 2020, including advanced refunds, as well as all credits under section 2301 of the CARES Act that are refunded on or after March 13, 2020, including advanced refunds.

Special Analyses

The Office of Management and Budget's Office of Information and Regulatory Analysis has determined that these temporary regulations are not significant and not subject to review under section 6(b) of Executive Order 12866.

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), the Secretary certifies that these temporary regulations will not have a significant economic impact on a substantial number of small entities because these temporary regulations impose no compliance burden on any business entities, including small entities. Although these temporary regulations will apply to all employers eligible for the credits under the Families First Act and the CARES Act, including small businesses and tax-exempt organizations with fewer than 500 employees, and will therefore be likely to affect a substantial number of small entities, the economic impact will not be significant. These temporary regulations do not affect the employer's employment tax reporting or the necessary information to substantiate entitlement to the credits. Rather, these temporary regulations merely implement the statutory authority granted under sections 7001(f) and 7003(f) of the Families First Act and section 2301(l) of the CARES Act that authorize the IRS to assess, reconcile, and recapture any portion of the credits erroneously credited, paid, or refunded in excess of the actual amount allowed as if the amounts were tax liabilities under sections 3111(a) and 3221(a) subject to assessment and administrative collection procedures. Notwithstanding this certification, the Treasury Department and the IRS invite comments on any impact these temporary regulations would have on small entities.

Pursuant to section 7805(f), these temporary regulations have been submitted to the Chief Counsel of the Office of Advocacy of the Small Business Administration for comment on its impact on small business.

The Treasury Department and the IRS have determined that good cause exists under section 553(b)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*). Section 553(b)(B) provides that an agency is not required to publish a notice of proposed rulemaking in the **Federal Register** when the agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. Employers must file Form 941, *Employer's Quarterly Federal Tax Return,* for the second quarter of calendar year 2020 by July 31, 2020, as required by section 6071 of the Code and Treas. Reg. § 31.6071(a)–1. Employers use Form 941 to claim qualified leave credits under the Families First Act and the employee retention credit under the CARES Act, as well as to report any advance of these credits they received during the quarter. In filing their second quarter 2020 Form 941, some employers will report and receive, or will have already received as an advance, refund amounts in excess of the refund to which they are entitled. These temporary regulations authorize the assessment of any such erroneous refunds. Without these temporary regulations, in some instances the IRS may not be able to avoid bringing costly and burdensome litigation to recover such reported erroneous refunds. Further, comments are being solicited in the cross-referenced notice of proposed rulemaking that is in this issue of the **Federal Register**, and any comments will be considered before final regulations are issued.

Statement of Availability of IRS Documents

IRS notices and other guidance cited in this preamble are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *http://www.irs.gov.*

Drafting Information

The principal author of these temporary regulations is NaLee Park, Office of the Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes). However, other personnel from the Treasury Department and the IRS participated in the development of these temporary regulations.

List of Subjects in 26 CFR 31

Employment taxes, Income taxes, Penalties, Pensions, Railroad retirement, Reporting and recordkeeping requirements, Social security, Unemployment compensation.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 31 is amended as follows:

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT SOURCE

■ **Paragraph 1.** The authority citation for part 31 is amended by adding entries for §§ 31.3111–6T and 31.3221–5T in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805.

* * * * *

Section 31.3111–6T also issued under sec. 7001 and sec. 7003 of the Families First Coronavirus Response Act of 2020 and sec. 2301 of the Coronavirus Aid, Relief, and Economic Security Act of 2020.

* * * * *

Section 31.3221–5T also issued under sec. 7001 and sec. 7003 of the Families First Coronavirus Response Act of 2020 and sec. 2301 of the Coronavirus Aid, Relief, and Economic Security Act of 2020.

* * * * *

■ **Par. 2.** Section 31.3111–6T is added to read as follows:

§ 31.3111–6T Recapture of credits under the Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security Act.

(a) *Recapture of erroneously refunded credits under the Families First Coronavirus Response Act.* Any amount of credits for qualified sick leave wages or qualified family leave wages under sections 7001 and 7003, respectively, of the Families First Coronavirus Response Act (Families First Act), Public Law 116–127, 134 Stat. 178 (2020), as modified by section 3606 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116–136, 134 Stat. 281 (2020), plus any amount of credits for qualified health plan expenses under sections 7001 and 7003, and including any increases in those credits under section 7005 of the Families First Act, that are treated as overpayments and refunded or credited to an employer under section 6402(a) or section 6413(b) of the Internal Revenue Code (Code) and to which the employer is not entitled, resulting in an erroneous refund to the employer, shall be treated as an underpayment of the taxes imposed by section 3111(a) of the Code and may be assessed and collected by the Secretary in the same manner as the taxes.

(b) *Recapture of erroneously refunded credits under the Coronavirus Aid, Relief, and Economic Security Act.* Any amount of credits for qualified wages under section 2301 of the CARES Act

that is treated as an overpayment and refunded or credited to an employer under section 6402(a) or section 6413(b) of the Code and to which the employer is not entitled, resulting in an erroneous refund to the employer, shall be treated as an underpayment of the taxes imposed by section 3111(a) of the Code and may be assessed and collected by the Secretary in the same manner as the taxes.

(c) *Advance credit amounts erroneously refunded.* The determination of any amount of credits erroneously refunded as described in paragraphs (a) and (b) of this section must take into account any amount of credits advanced to an employer under the process established by the Internal Revenue Service in accordance with sections 7001(b)(4)(A)(ii) and 7003(b)(3)(B) of the Families First Act, as modified by section 3606 of the CARES Act, and section 2301(l)(1) of the CARES Act.

(d) *Third party payors.* For purposes of this section, employers against whom an erroneous refund of the credits under sections 7001 and 7003 of the Families First Act (including any increases in those credits under section 7005 of the Families First Act), as modified by section 3606 of the CARES Act, and the credits under section 2301 of the CARES Act can be assessed as an underpayment of the taxes imposed by section 3111(a) include persons treated as the employer under sections 3401(d), 3504, and 3511 of the Code, consistent with their liability for the section 3111(a) taxes against which the credit applied.

(e) *Applicability date.* This regulation applies to all credit refunds under sections 7001 and 7003 of the Families First Act (including any increases in those credits under section 7005 of the Families First Act), as modified by section 3606 of the CARES Act, advanced or paid on or after April 1, 2020 and all credit refunds under section 2301 of the CARES Act advanced or paid on or after March 13, 2020.

■ **Par. 3.** Section 31.3221–5T is added to read as follows:

§ 31.3221–5T Recapture of credits under the Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security Act.

(a) *Recapture of erroneously refunded credits under the Families First Coronavirus Response Act.* Any amount of credits for qualified sick leave wages or qualified family leave wages under sections 7001 and 7003, respectively, of the Families First Coronavirus Response Act (Families First Act), Public Law 116–127, 134 Stat. 178 (2020), as modified by section 3606 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116–136, 134 Stat. 281 (2020), plus any amount of credits for qualified health plan expenses under sections 7001 and 7003, that are treated as overpayments and refunded or credited to an employer under section 6402(a) or section 6413(b) of the Internal Revenue Code (Code) and to which the employer is not entitled, resulting in an erroneous refund to the employer, shall be treated as an underpayment of the taxes imposed by section 3221(a) of the Code and may be assessed and collected by the Secretary in the same manner as the taxes.

(b) *Recapture of erroneously refunded credits under the Coronavirus Aid, Relief, and Economic Security Act.* Any amount of credits for qualified wages under section 2301 of the CARES Act that is treated as an overpayment and refunded or credited to an employer under section 6402(a) or section 6413(b) of the Code and to which the employer is not entitled, resulting in an erroneous refund to the employer, shall be treated as an underpayment of the taxes imposed by section 3221(a) of the Code and may be assessed and collected by the Secretary in the same manner as the taxes.

(c) *Advance credit amounts erroneously refunded.* The determination of any amount of credits erroneously refunded as described in paragraphs (a) and (b) of this section must take into account any amount of credits advanced to an employer under the process established by the Internal Revenue Service in accordance with sections 7001(b)(4)(A)(ii) and 7003(b)(3)(B) of the Families First Act, as modified by section 3606 of the CARES Act, and section 2301(l)(1) of the CARES Act.

(d) *Third party payors.* For purposes of this section, employers against whom an erroneous refund of the credits under sections 7001 and 7003 of the Families First Act, as modified by section 3606 of the CARES Act, and the credits under section 2301 of the CARES Act can be assessed as an underpayment of the taxes imposed by section 3221(a) include persons treated as the employer under sections 3401(d), 3504, and 3511 of the Code, consistent with their liability for the section 3221(a) taxes against which the credit applied.

(e) *Applicability date.* This regulation applies to all credit refunds under sections 7001 and 7003 of the Families First Act, as modified by section 3606 of the CARES Act, advanced or paid on or after April 1, 2020, and all credit refunds under section 2301 of the CARES Act advanced or paid on or after March 13, 2020.

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

Approved: July 14, 2020.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2020–16302 Filed 7–24–20; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2020–0408]

RIN 1625–AA00

Emergency Safety Zone; Lower Mississippi River, Helena, AR

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone for emergency purposes for all waters of the Lower Mississippi River (LMR), extending from mile 660.0 to mile 663.0. This emergency safety zone is needed to protect persons, property, and infrastructure from the potential safety hazards associated with the diving and salvage effort of a sunken barge at Mississippi River Mile Marker (MM) 661.0, in the vicinity of the Helena Highway Bridge, Helena, Arkansas. Deviation from the safety zone is prohibited unless specifically authorized by the Captain of the Port Lower Mississippi River or a designated representative.

DATES: This rule is effective without actual notice from July 29, 2020 through August 30, 2020, or until all diving and salvage work is complete, whichever occurs earlier. For the purposes of enforcement, actual notice will be used from July 13, 2020 through July 29, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0408 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Adam J. Paz, U.S. Coast Guard; telephone 901–521–4825, email *adam.j.paz@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because salvage efforts for a sunken barge mid-river will impede the safe navigation of vessel traffic and immediate action is needed to protect persons and property. Completing the full NPRM process is impracticable because we must establish this safety zone immediately.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest because immediate action is needed to respond to the potential safety hazards associated with salvage operations in the vicinity of the Helena Highway Bridge.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port (COTP) Lower Mississippi River has determined that potential hazards associated with the salvage of a sunken barge will be a safety concern for anyone within a one-mile radius of the salvage operation. This rule is needed to protect persons, property, and infrastructure from the potential safety hazards associated with the diving and salvage effort of a sunken barge at Mississippi River Mile Marker (MM) 661.0, in the vicinity of the Helena Highway Bridge from July 13, 2020 through August 30, 2020, or until all diving and salvage work is complete, whichever occurs earlier.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from July 13, 2020 through August 30, 2020, or until all diving and salvage work is complete, whichever occurs earlier. The safety zone will cover all navigable waters of the Mississippi River from MM 660.0 to MM 663.0, extending the entire width of the river. The safety zone will only be activated when salvage work precludes safe navigation of the established channel. The duration of the zone is intended to protect persons, property, and infrastructure in these navigable waters while the salvage work is being conducted. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of the safety zone. This emergency safety zone will temporarily restrict navigation on the Mississippi River from MM 660.0 through MM 663.0 in the vicinity of Helena, Arkansas, from July 13, 2020 through August 30, 2020, or until all diving and salvage work is complete, whichever occurs earlier. The Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 informing the public that the zone will be activated, and the rule would allow vessels to seek permission to enter the zone on a case-by-case basis.

B. Impact on Small Entities

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

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism

principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves an emergency safety zone on the Mississippi River from MM 660.0 through MM 663.0, that will prohibit entry into this zone unless permission has been granted by the COTP Lower Mississippi River or a designated representative. The safety zone will only be enforced during short durations while salvage work precludes the safe navigation of the established channel. It is categorically excluded from further review under paragraph L60(d) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS.

■ 1. The authority citation for Part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0408 to read as follows:

§ 165.T08–0408 Emergency Safety Zone; Lower Mississippi River, Helena, AR.

(a) *Location.* The following area is a safety zone: All waters of the Mississippi River from MM 660.0 through MM 663.0.

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

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

(c) *Enforcement periods.* This section will be enforced as needed from July 13, 2020 through August 30, 2020, or until all diving and salvage work is complete, whichever occurs earlier. Periods of activation will be promulgated by Broadcast Notice to Mariners.

Dated: July 13, 2020.

R.S. Rhodes,

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

[FR Doc. 2020–15888 Filed 7–28–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2020–0444]

RIN 1625–AA87

Security Zone; North Atlantic Ocean, Approaches to Ocean City, MD

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone encompassing certain waters of the North Atlantic Ocean. The security zone is necessary to prevent waterside threats before, during, and after National Geospatial-Intelligence Agency equipment testing conducted offshore near Ocean City, MD. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Maryland-National Capital Region or his designated representative.

DATES: This rule is effective without actual notice from July 29, 2020 through 9:30 p.m. on August 28, 2020. For the purposes of enforcement, actual notice will be used from 9 a.m. on July 27, 2020, through July 29, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0444 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Ron Houck, Sector Maryland-National Capital Region Waterways Management Division, U.S. Coast Guard; telephone 410–576–2674, *Ronald.L.Houck@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5

U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it would be impracticable and contrary to the public interest. The Coast Guard was unable to publish an NPRM and hold a comment period for this rulemaking due to the short time period between event planners notifying the Coast Guard of the event and required publication of this security zone. It is necessary for the Coast Guard to establish this security zone by July 27, 2020, in order to ensure the appropriate level of waterborne protection for the public, mitigation of potential terrorist acts, and enhancing maritime safety and security in order to safeguard life, property, and the environment.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest for the same reasons discussed above for forgoing notice and comment.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP Maryland-National Capital Region has determined that a security zone is needed for waterborne protection of the public, mitigation of potential terrorist acts, and the enhancing of public and maritime safety and security in order to safeguard life, property, and the environment on or near the navigable waters near Ocean City, MD.

IV. Discussion of the Rule

This rule establishes a security zone from 9 a.m. on July 27, 2020, through 9:30 p.m. on August 28, 2020. The security zone will be enforced from 9 a.m. to 9:30 p.m. on July 27, 2020, and those same hours on July 28, 2020, July 29, 2020, July 30, 2020, July 31, 2020, August 24, 2020, August 25, 2020, August 26, 2020, August 27, 2020, and August 28, 2020. The security zone will cover all waters of the North Atlantic Ocean, from surface to bottom, encompassed by a line connecting the following points beginning at 38°23′56″ N, 074°48′06″ W, thence south to 38°21′40″ N, 074°48′33″ W, thence south to 38°17′54″ N, 074°49′57″ W, thence southwest to 38°15′04″ N, 074°51′44″ W, thence northwest to 38°18′52″ N, 074°54′24″ W, thence north to 38°22′55″ N, 074°52′44″ W, and northeast back to the beginning point. The zone is approximately 9.3 nautical miles yards in length and 3.6 nautical miles yards in width. If a person or vessel has been granted permission to enter the zone, while they are operating in the zone that they must not enter waters within 1,000 yards of the on scene Coast Guard vessel or test equipment being used by Coast Guard personnel.

The duration of the rule and enforcement of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the Coast Guard vessel and test equipment are being used. All vessels and persons must obtain permission from the COTP Maryland-National Capital Region or his designated representative before entering the security zone. Equipment testing operations may occur anywhere within the security zone during the enforcement periods. Vessels and persons will not be permitted to enter the security zone within 1,000 yards of the Coast Guard vessel or test equipment. While this 1,00- yards area lies within the security zone, its exact location within the security zone may change.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the location and duration of the security zone. This security zone will be enforced 125 hours over the course of a one month period. Vessels will be able to safely transit around the security zone, which impacts a small area of the North Atlantic Ocean, where vessel traffic is normally low. Additionally, the Coast Guard will make notifications to the maritime community via marine information broadcasts. The Coast Guard will update such notifications as necessary to keep the maritime community informed of the status of the security zone.

B. Impact on Small Entities

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

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the

Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a security zone lasting only 125 total enforcement hours that will prohibit entry within a small portion of the North Atlantic Ocean. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–0444 to read as follows:

§ 165.T05–0444 Security Zone; North Atlantic Ocean, Approaches to Ocean City, MD.

(a) *Location.* The following is a security zone: All waters of the North Atlantic Ocean, from surface to bottom, encompassed by a line connecting the following points beginning at 38°23′56″ N, 074°48′06″ W, thence south to 38°21′40″ N, 074°48′33″ W, thence south to 38°17′54″ N, 074°49′57″ W, thence southwest to 38°15′04″ N, 074°51′44″ W, thence northwest to 38°18′52″ N, 074°54′24″ W, thence north to 38°22′55″ N, 074°52′44″ W, and northeast back to the beginning point. All coordinates are based on datum NAD 83.

(b) *Definitions.* As used in this section—

Captain of the Port (COTP) means the Commander, U.S. Coast Guard Sector Maryland-National Capital Region.

Designated representative means the Coast Guard commissioned, warrant, or petty officer operating the on scene Coast Guard vessel designated by or assisting the Captain of the Port Maryland-National Capital Region (COTP) in the enforcement of the security zone.

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

(2) To seek permission to enter the security zone described in paragraph (a) of this section, contact the COTP or the COTP's representative by telephone at 410–576–2693 or on Marine Band Radio VHF–FM channel 16 (156.8 MHz). The Coast Guard vessel enforcing this section can be contacted on Marine Band Radio VHF–FM channel 16 (156.8 MHz). Those in the security zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(3) A person or vessel operating in the security zone described in paragraph (a)(1) of this section must not enter waters within 1,000 yards of the on scene Coast Guard vessel or test equipment being used by Coast Guard personnel.

(d) *Enforcement periods.* This section will be enforced 9 a.m. to 9:30 p.m. on July 27, 2020, and those same hours on July 28, 2020, July 29, 2020, July 30, 2020, and July 31, 2020, August 24, 2020, August 25, 2020, August 26, 2020, August 27, 2020, and August 28, 2020.

Dated: July 23, 2020.

Joseph B. Loring,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2020–16367 Filed 7–28–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2020–0437]

RIN 1625–AA00

Safety Zone; Fireworks Display; Fox River, Green Bay, WI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters of the Fox River in Green Bay, WI. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards from a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port (COTP) Lake Michigan.

DATES: This rule is effective from 8 p.m. through 10 p.m. on August 1, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0437 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Chief Petty Officer Kyle Weitzell, Sector Lake Michigan Waterways Management Division, U.S. Coast Guard; telephone 414–747–7148, email *Kyle.W.Weitzell@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a Notice of Proposed Rulemaking (NPRM) with respect to this rule because it is impracticable to do so. Notice of this event was submitted to the Coast Guard on July 6, 2020 and publishing a NPRM would delay the creation of this safety zone in time for the scheduled fireworks display on August 1, 2020.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to enact a safety zone associated with a fireworks display on August 1, 2020.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP Lake Michigan has determined that potential hazards associated with fireworks over the Fox River on August 1, 2020 will be a safety concern for anyone within a 500-foot radius of the launch site. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the fireworks are being launched.

IV. Discussion of the Rule

This rule establishes a safety zone from 8 p.m. through 10 p.m. on August 1, 2020. The safety zone will cover all navigable waters of the Fox River within a 500-foot radius of coordinates 44°31.15′ N, 088°00.86′ W. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the fireworks are being launched. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP Lake Michigan or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of this proposed safety zone. This regulation will be in effect on the Fox River within 500 feet of a fireworks display on August 1, 2020 for no more than two hours. Additionally, the COTP Lake Michigan may consider the movement of persons and vessels through or within the safety zone, if it is safe to do so.

B. Impact on Small Entities

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

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination

with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only two hours that will prohibit entry within 500 feet of a fireworks display the Fox River. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0437 to read as follows:

§ 165.T09–0437 Safety Zone; Fireworks Display; Fox River, Green Bay, WI.

(a) *Location.* All navigable waters of Fox River in Green Bay, WI within 500 feet of fireworks launch site at coordinates 44°31.15′ N, 088°00.86′ W.

(b) *Enforcement Period.* This rule will be enforced from 8 p.m. through 10 p.m. on August 1, 2020.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Sector (COTP) Lake Michigan or a designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the COTP Lake Michigan or a designated on-scene representative.

(3) The ''on-scene representative'' of the COTP Lake Michigan is any Coast Guard commissioned, warrant or petty officer who has been designated by the COTP Lake Michigan to act on his or her behalf.

(4) Vessel operators desiring to enter or operate within the safety zone must contact the COTP Lake Michigan or an on-scene representative to obtain permission to do so. The COTP Lake Michigan or an on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP Lake Michigan or an on-scene representative.

Dated: July 17, 2020.

D.P. Montoro,

Captain, U.S. Coast Guard, Captain of the Port Lake Michigan.

[FR Doc. 2020–15884 Filed 7–28–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF EDUCATION

34 CFR Chapter III

[ED–2019–OSERS–0001]

Final Priority and Definitions—State Personnel Development Grants

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education.

ACTION: Final priority and definitions.

SUMMARY: The Department of Education (Department) announces a priority and definitions under the State Personnel Development Grants program, Catalog of Federal Domestic Assistance (CFDA) number 84.323A. The Department may use this priority and definitions for competitions in fiscal year (FY) 2020 and later years. We take this action to focus attention on an identified national need to provide teachers and other personnel who serve children with disabilities the option to select professional development activities that will best meet their needs. This priority will support States in developing pilots or other innovative means of providing choice in professional development.

DATES: *Effective Date:* This priority and definitions are effective August 28, 2020.

FOR FURTHER INFORMATION CONTACT: Jennifer Coffey, U.S. Department of Education, 400 Maryland Avenue SW, Room 5161, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 245–6673. Email: *jennifer.coffey@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: *Purpose of Program:* The purpose of the State Personnel Development Grants program is to assist State educational agencies (SEAs) in reforming and improving their systems for personnel preparation and professional development in early intervention, educational, and transition services in order to improve results for children with disabilities.

Program Authority: 20 U.S.C. 1451–1455.

We published a notice of proposed priority and definitions (NPP) for this program in the **Federal Register** on April 24, 2020 (85 FR 22972). The NPP contained background information and our reasons for proposing the particular priority and definitions.

There are minor differences between the NPP and this notice of final priority and definitions (NFP) as discussed in

the *Analysis of Comments and Changes* section of this notice.

Public Comment: In response to our invitation in the NPP, 18 parties submitted comments on the proposed priority and definitions. Generally, we do not address technical and other minor changes. In addition, we do not address comments that raised concerns not directly related to the proposed priority and definitions. An analysis of the comments and of any changes in the priority and definitions since publication of the NPP follows.

Analysis of Comments and Changes

Comment: Several commenters, especially personnel who have heavy or challenging workloads, expressed concern that some teachers and other personnel could not readily assess their professional development needs and thus not improve critical skills for serving children with disabilities. A few commenters shared that within a multi-tiered system of support, student and school data are analyzed to determine professional development needs and that the proposed priority did not lend itself to a data-based approach to choosing professional development options. Some commenters specified that students with disabilities need coordinated efforts between administrators, teachers, and other personnel and that allowing individuals to choose their professional development activities would prevent a coordinated approach.

Discussion: The Department appreciates the responses to the NPP. The Department believes that States and local agencies and programs will develop innovative ways to support personnel in assessing their needs and connecting those needs with effective professional development choices. Additionally, two other priorities for this program—the State Personnel Development Grants (SPDG) statutory priority from sections 651 through 655 of the Individuals with Disabilities Education Act (IDEA), as amended by the Every Student Succeeds Act (ESSA), and the priority for this program published in the **Federal Register** on August 2, 2012 (77 FR 45944) related to the effective and efficient delivery of personnel development—are priorities that lend themselves to a data-driven and coordinated approach for assessing and providing professional development needs to assist personnel who work with children with disabilities. Because we expect to use the Choice in Professional Development priority in combination with both of the other two priorities, at this time, the Department does not believe changes to the Choice in Professional Development priority are warranted.

Changes: None.

Comment: One commenter expressed concern that teachers and other personnel would have a difficult time determining the appropriate interventions for the children with disabilities they serve.

Discussion: The proposed Choice in Professional Development priority is not meant to replace the two SPDG priorities discussed above, which focus activities on identified needs in the State, such as assisting teachers and other personnel in choosing effective interventions to improve the outcomes of children with disabilities. As described in the NPP, a State could use this new priority to support local agencies and programs in selecting a subset of personnel who work with children with disabilities to choose their professional development activities. These could be practitioners who have demonstrated success in selecting interventions and who desire to increase their skills in a specific area, such as leadership. Or it could be a group of personnel, such as teachers of children who are deaf and blind, who have unique professional development needs.

Changes: None.

Comment: Several commenters spoke to the continued need for a systemic approach, including the use of implementation science, when meeting professional development needs. Systemic preparation and professional development plans that address State and local needs were noted as critical for large scale improvement. Additionally, commenters noted that planning for use of SPDG funds must include a cadre of important stakeholders, such as educators, principals, administrators, related services personnel, early intervention personnel and others. The commenters expressed concern that the new priority would not support this planning process and would undermine both the requirements of the law and important planning and alignment between the use of the SPDG funding and the SEA's goals for its education standards, certification requirements, and continuing education that systematically address State and local needs.

Discussion: While the Department appreciates the commenters' concerns, we also believe that this priority could enable SEAs to strengthen their professional development activities consistent with State and local personnel needs. Pilot efforts supported under this priority could be part of a larger professional development system that uses SPDG funds to reform and improve personnel development throughout the State. Planning for use of SPDG funds, described by the SPDG statutory priority from sections 651 through 655 of IDEA, as amended by the ESSA, requires planning with key stakeholders such as those listed by the commenters. Identifying local educational agencies (LEAs) and early childhood programs where choice in professional development may be most useful could be determined during this planning as well. Providing professional development choice for personnel within the systemic SPDG effort may increase States' impact on personnel practice and thus on child outcomes. The SPDG statutory priority requires States to assess their needs and align their goals with those needs, as appropriate. These requirements apply equally to the Choice in Professional Development priority.

In response to concerns related to implementation science, the SPDG Government Performance Results Modernization Act of 2010 (GPRA) measures require projects to assess their use of implementation science principles when developing a professional development system. Specifically, an evidence-based professional development rubric is used to measure projects' use of implementation science strategies in their professional development activities. Additionally, projects use intervention fidelity measures to demonstrate changes in personnel practice as a result of participation in professional development. Finally, the effort provided for coaching or mentoring supports is reported by projects. The Department intends to use these GPRA measures for funded projects that respond to the Choice in Professional Development priority.

Changes: We have added requirements aligned with the GPRA measures for applicants responding to the Choice in Professional Development priority. The added requirements are in paragraph (e) under the *Final Priority* section of the NFP.

Comment: A number of commenters expressed concern that having individuals choose their professional development activities would prevent States from working toward a larger collective goal, such as increasing teachers' expectations for children with disabilities. In addition, commenters stated that the proposed priority would be a deterrent to using SPDG funds for results-driven accountability and efforts related to the State Systemic Improvement Plan (SSIP).

Discussion: The Department agrees with the commenters that it is important for State agencies to work toward larger goals. All applicants must address the SPDG statutory priority that requires projects to identify and address the State and local needs for the personnel preparation and professional development of personnel, as well as individuals who provide direct supplementary aids and services to children with disabilities. The needs may align with the needs identified for the SSIP, and the SPDG professional development activities could be used to help reach the State-identified measurable result. Accordingly, the Department does not believe further clarification of the proposed priority is warranted.

Changes: None.

Comment: Some commenters were unsure how the impact of professional development activities would be assessed under this priority. The commenters specified that all professional development efforts should be chosen based on need and effectiveness data and that intervention fidelity and impact on child outcomes should be assessed.

Discussion: The Department agrees with the commenters regarding the need to assess the impact of the professional development activities on personnel skills and the corresponding improvement in child outcomes. The SPDG GPRA measures include both a measure of implementation fidelity and a measure of child outcomes. The Department intends to use these GPRA measures for funded projects that respond to the Choice in Professional Development priority.

Changes: We have added requirements aligned with the GPRA measures for applicants responding to the Choice in Professional Development priority. The added requirements are in paragraph (e) under the *Final Priority* section of the NFP.

Comment: Several commenters described the importance of aligning individuals' professional development with local program, school, district, and State initiatives and the need for the State and local entities to coordinate their efforts. Further, a number of commenters described the importance of a coordinated and integrated approach to professional development that encourages collaboration across personnel who work with children with disabilities. Specifically, the commenters described how teams working with children with disabilities benefit from a coordinated set of skills and knowledge and how individually chosen professional development activities might detract from a cohesive approach.

Discussion: The Department agrees that aligning professional development activities with early childhood program, school, district, region, and State priorities and improvement efforts is important. Under this priority, local programs and districts could provide a menu of professional development activities that could assist teachers and other personnel in developing their skills in areas that align with their State or local agency's improvement efforts. The Department believes that an innovative approach to providing choice that aligns those choices with ongoing improvement efforts is possible. Further, the Department fully supports coordinating efforts at all levels of the early childhood and education systems.

Also, the Department agrees that the teams supporting children with disabilities should take a coordinated approach in their efforts. The individuals on that team, however, may have varying professional development needs. The structure of the team provides an opportunity to bring the diverse skills and knowledge of the team members together in a way that best serves the needs of the child. Accordingly, the Department does not believe changes to the priority are necessary.

Changes: None.

Comment: Some commenters stated that State policies concerning certification requirements and LEA priorities cannot and should not be superseded by individuals' professional development choices. Additionally, some of these commenters expressed concern about administrators no longer having authority over the professional development choices of their staff and that this would strip administrators of the ability to be instructional leaders.

Discussion: The Choice in Professional Development priority does not supersede State and local certification requirements or the ability of administrators to choose the professional development activities provided to personnel. Personnel will continue to be subject to State and local certification requirements, and administrators retain existing authority to mandate professional development activities. Under the Choice in Professional Development priority, an administrator could create a menu of choices for personnel who work with children with disabilities or identify another way to ensure the choices available align with the administrative priorities at the local and State levels, as appropriate. Providing choices to individuals do not preclude the involvement of administrators or alignment with larger improvement efforts. Therefore, the Department does not believe changes to the priority are necessary.

Changes: None.

Comment: A few commenters asked how a State could scale the professional development found to be effective under this priority.

Discussion: The Department believes that States and local agencies and programs will find innovative ways to integrate effective professional development activities into their overall SPDG efforts. For example, if an intensive literacy approach is found to be effective in improving reading ability for children with disabilities and SPDG funds are being used to implement a multi-tiered system of supports (MTSS), the intensive literacy approach could be integrated into the larger MTSS effort.

Changes: None.

Comment: One commenter asked that we incorporate into the priority the concept of ''personnel instructional autonomy,'' which the commenter defined as possessing meaningful choice and voice in choosing high-quality evidence-based professional development in a comprehensive system. The commenter further suggested that student outcome and school fidelity data be used to determine the areas where schools and districts focus for professional development and that State standards for students guide teacher choice and voice.

Discussion: The Department agrees with the essence of the description the commenter provided. This description corresponds with the Department's perspective on the importance of providing meaningful choice in professional development. States have the option to create an operational definition of choice consistent with the needs of personnel in their State. Therefore, it is not necessary for the Department to provide a definition of choice for this priority.

Changes: None.

Comment: One commenter stated that the priority would prevent States from preparing personnel and further developing their skills. Other commenters shared that having a structure in place for ongoing teacher support and enrichment, beyond the initial training they receive, is vital if teachers are to implement evidence-based practices with fidelity. They expressed concern that ongoing support in the form of coaching or professional learning communities cannot be adequately addressed when personnel

have autonomy in making their professional development choices.

Discussion: The Department expects that States and local agencies and programs will develop innovative ways to provide personnel with professional development options that prepare them to meet the needs of children with disabilities. Professional development options will need to provide fidelity measures for the practices or programs that are the focus of the professional development activities. Consistent with new program application requirements, the professional development activities chosen must have fidelity measurement tools that coaches or professional learning communities can then use to assess implementation and connect that implementation to impact on child outcomes.

Changes: None.

Comment: Some commenters stated that the SPDG should contribute to the education infrastructure and that this priority dilutes the limited SPDG resources. They recommended that SPDG funds be focused to have the largest systemic impact possible and expressed concern that providing special education teachers and other personnel the autonomy to select professional development activities based on their individual needs will prove disruptive and detrimental to the core purpose of the SPDG program.

Discussion: This priority is provided to assist States and local agencies in fully engaging in the professional development of teachers and other personnel who serve children with disabilities. For the reasons explained throughout the Department's responses to previous comments, the Department does not agree that this priority will undermine the purpose of the SPDG program. Accordingly, the Department does not believe that changes to the priority are needed.

Changes: None.

Comment: One commenter was concerned that rural personnel would not be able to make use of professional development choice.

Discussion: Online synchronous and asynchronous training and coaching have become more available and more effective in recent years (Coogle et al., 2018; Gregory et al., 2017). Personnel in rural areas could access training and coaching virtually, as appropriate, and as such, the Department does not believe this priority prohibits participation from rural personnel.

Changes: None.

Comment: One commenter stated that this priority did not meet the rigorous standard for professional development under the Elementary and Secondary Education Act, as amended (ESEA), and adopted by IDEA and would not support professional learning that is sustained, collaborative, school-based, and job-embedded. Other commenters felt that the professional development described in the priority does not meet best practice standards for effective professional development.

Discussion: The Department expects that States and local entities will work together to provide professional development choices that are sustained and that support the important work of teachers and other personnel who serve children with disabilities. Additionally, collaborative efforts, such as professional learning communities, should remain intact. Personnel who receive professional development under this priority will be assessed for the fidelity of implementation for the professional development options they choose. These personnel should receive coaching or mentoring, and should have the opportunity to review fidelity and child data with fellow practitioners. The professional learning offered in response to this funding priority must comply with the standards in the ESEA and IDEA, as amended by ESSA, as applicable. For these reasons, the Department believes that SPDG projects will continue to meet best practice standards.

Changes: None.

Comment: A few commenters felt the standard for evidence set for professional development activities was too low.

Discussion: Applications for this discretionary program undergo a rigorous peer review. The reviewers have expertise in professional development and will use this expertise to assess proposed projects based on their ability to meet the program requirements, as well as the extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the beneficiaries of those services.

Changes: None.

Comment: A few commenters expressed there was not sufficient evidence to support choice in professional development as described in this priority.

Discussion: Sparks and Malkus (2015) found evidence that teacher autonomy is positively associated with teachers' job satisfaction and teacher retention (Guarino, Santibañez, and Daley 2006; Ingersoll and May 2012). The Department seeks to improve the retention of personnel by supporting personnel choice.

Changes: None.

Comment: Some commenters contended this priority would place an undue burden on States. One of these commenters felt it would be exceptionally difficult for new applicants to respond to the priority. Another commenter was concerned that evaluating individual teachers' professional development activities would be impractical for States, especially more rural States.

Discussion: This priority is provided to assist States with fully engaging teachers and other personnel who serve children with disabilities in their professional development. Participation in this program is voluntary, and the costs imposed on applicants by this regulatory action will be limited to the paperwork burden related to preparing an application, as the costs of carrying out activities associated with the application will be paid for with program funds. Accordingly, the Department does not believe that changes to the priority are needed.

Changes: None.

Comment: One commenter shared that Parent Centers bring direct experience and expertise in family engagement to the learning and experiences of personnel. The commenter contended it would be extremely difficult to bring this experience, expertise, and perspective to an individual stipend program under the priority.

Discussion: The Department agrees that family engagement is critical to the success of all children, and especially children with disabilities. The requirement that an SPDG project must contract or subgrant with an OSEP-funded parent training and information center (PTI), or community parent resource center (CPRC), as appropriate, remains intact and family engagement remains a focus for all SPDG priorities. Planning for this work with key stakeholders, such as family members of children with disabilities and parent centers, continues to be a requirement under the SPDG statutory priority.

Changes: None.

References

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Guarino, C.M., Santibañez, L., and Daley, G.A. (2006). Teacher Recruitment and Retention: A Review of the Recent Empirical Literature. *Review of Educational Research, 76,* 173–208.

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Final Priority

Choice in Professional Development

The purpose of this priority is to fund SPDG grants to SEAs that empower teachers and other personnel to select professional development activities that meet their individual needs to improve results for children with disabilities. States will meet the priority if they describe in their application how they will develop personalized professional development projects to carry out their State plan under section 653 of IDEA and implement professional development activities that are consistent with the use of funds provisions in section 654 of IDEA. This would be accomplished by using funds under the SPDG program for stipends or other mechanisms to provide personnel with choice in selecting professional development options that will count toward State or local professional development requirements, as appropriate, such as the number of hours personnel must fill or the competencies they must acquire to obtain or retain certification, and that are designed to meet their individual needs and thus improve results for children with disabilities.

Applicants must—

(a) Demonstrate, in the narrative section of the application under ''Significance,'' how the proposed project will develop personalized professional development activities using stipends or other mechanisms that provide personnel choice in professional development options designed to meet their individual needs and count toward State or local professional development requirements and thus improve results for children with disabilities;

(b) Describe how the State will select the individual(s) or groups of personnel that will be provided with professional development options, including the extent to which applicants will prioritize selecting individuals or groups of personnel serving rural children with disabilities or disadvantaged children with disabilities, such as children from low-income families. If applicable, applicants should specify how they will prioritize personnel if demand for professional development among the individuals or groups of personnel that the applicant proposes to serve exceeds what available funds can support;

(c) Describe how the State will create a list of approved professional development options that meet the requirements of the SPDG program. This description should include how the applicant will engage with a range of stakeholders, including school administrators, personnel serving students with disabilities, families of students with disabilities and individuals with disabilities, and other State or local agencies serving individuals with disabilities, such as juvenile justice agencies, to determine which professional development options it will offer. Specifically, professional development options must—

(1) Use evidence-based (as defined in this notice) professional development methods that will increase implementation of evidence-based practices and result in improved outcomes for children with disabilities;

(2) Include ongoing assistance that supports the implementation of evidence-based practices with fidelity (as defined in this notice); and

(3) Use technology to more efficiently and effectively provide ongoing professional development to personnel, including to personnel in rural areas and in urban or high-need local educational agencies (LEAs) (as defined in this notice);

(d) If applicable, describe the steps that personnel would need to take to request professional development options not already on a list of approved professional development options, the justification that personnel would need to provide to demonstrate how the selected options would improve results for children with disabilities, and how personnel would be notified if their request was approved or disapproved in writing and within 14 days; and

(e) Describe—

(1) The extent to which the proposed project will use professional development practices supported by evidence to support the attainment of identified competencies;

(2) How improvement in implementation of SPDG-supported practices over time will be demonstrated by participants in SPDG professional development activities;

(3) The extent to which the proposed project will use SPDG professional development funds to provide activities designed to sustain the use of SPDG-supported practices;

(4) How the proposed project will determine whether special education teachers who meet the qualifications described in section 612(a)(14)(C) of IDEA, as amended by the ESSA, that have participated in SPDG-supported special education teacher retention activities remain as special education teachers two years after their initial participation in these activities; and

(5) How the proposed project will assess whether and to what extent the project improves outcomes for children with disabilities.

Types of Priorities

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

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

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

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

Final Definitions

The Department establishes the following definitions for use with this priority and requirements, and with the SPDG program. We establish these definitions to ensure that applicants have a clear understanding of how we are using these terms. We use definitions the Department has adopted elsewhere and provide the source of existing definitions in parentheses.

Evidence-based means the proposed project component is supported by one or more of strong evidence, moderate evidence, promising evidence, or evidence that demonstrates a rationale. (34 CFR 77.1)

Experimental study means a study that is designed to compare outcomes between two groups of individuals

(such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbook (version 3.0):

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment. (34 CFR 77.1)

Fidelity means the delivery of instruction in the way in which it was designed to be delivered. (77 FR 45944)

High-need LEA means, in accordance with section 2102(3) of the ESEA, an LEA—

(a) That serves not fewer than 10,000 children from families with incomes below the poverty line (as that term is defined in section 8101(41) of the ESEA), or for which not less than 20 percent of the children served by the LEA are from families with incomes below the poverty line; and

(b) For which there is (1) a high percentage of teachers not teaching in the academic subjects or grade levels that the teachers were trained to teach, or (2) a high percentage of teachers with emergency, provisional, or temporary certification or licensing.

Lead agency means the agency designated by the State's Governor under section 635(a)(10) of IDEA and 34 CFR 303.120 that receives funds under section 643 of IDEA to administer the State's responsibilities under part C of IDEA. (34 CFR 303.22)

Local educational agency (LEA) means a public board of education or other public authority legally constituted within a State for either administrative control or direction of, or to perform a service function for, public elementary schools or secondary schools in a city, county, township, school district, or other political subdivision of a State, or for such combination of school districts or counties as are recognized in a State as an administrative agency for its public elementary schools or secondary schools. (Section 602(19) of IDEA (20 U.S.C. 1401(19)))

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers). (34 CFR 77.1)

Promising evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome, based on a relevant finding from one of the following:

(i) A practice guide prepared by WWC reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single study assessed by the Department, as appropriate, that—

(A) Is an experimental study, a quasi-experimental design study, or a well-designed and well-implemented correlational study with statistical controls for selection bias (*e.g.,* a study using regression methods to account for differences between a treatment group and a comparison group); and

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome. (34 CFR 77.1)

Quasi-experimental design study means a study using a design that attempts to approximate an experimental study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.,* establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbook. (34 CFR 77.1)

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program. (34 CFR 77.1)

State educational agency (SEA) means the State board of education or other agency or officer primarily responsible for the State supervision of public elementary schools and secondary schools, or, if there is no such officer or agency, an officer or agency designated by the Governor or by State law. (Section 602(32) of IDEA (20 U.S.C. 1401(32)))

Strong evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations and settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1 or 3.0 of the WWC Handbook reporting a ''strong evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1 or 3.0 of the WWC Handbook reporting a ''positive effect'' on a relevant outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study reviewed and reported by the WWC using version 2.1 or 3.0 of the WWC Handbook, or otherwise assessed by the Department using version 3.0 of the WWC Handbook, as appropriate, and that—

(A) Meets WWC standards without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1 or 3.0 of the WWC Handbook; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy this requirement. (34 CFR 77.1)

What Works Clearinghouse Handbook (WWC Handbook) means the standards and procedures set forth in the WWC

Procedures and Standards Handbook, Version 3.0 or Version 2.1 (incorporated by reference, see 34 CFR 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the Handbook documentation. (34 CFR 77.1)

Note: The What Works Clearinghouse Procedures and Standards Handbook (Version 3.0), as well as the more recent What Works Clearinghouse Handbooks released in October 2017 (Version 4.0) and January 2020 (Version 4.1), are available at *https://ies.ed.gov/ncee/wwc/Handbooks.*

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

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

Executive Orders 12866, 13563, and 13771

Regulatory Impact Analysis

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

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

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

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

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

This final regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a ''major rule,'' as defined by 5 U.S.C. 804(2).

Under Executive Order 13771, for each new rule that the Department proposes for notice and comment or otherwise promulgates that is a significant regulatory action under Executive Order 12866, and that imposes total costs greater than zero, it must identify two deregulatory actions. For FY 2020, any new incremental costs associated with a new regulation must be fully offset by the elimination of existing costs through deregulatory actions. Because this regulatory action is not significant, the requirements of Executive Order 13771 do not apply.

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

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

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

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

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

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

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

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

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

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

Discussion of Potential Costs and Benefits

The Department believes that the costs associated with this final priority and definitions will be minimal, while the benefits are significant. The Department believes that this regulatory action does not impose significant costs on eligible entities. Participation in this program is voluntary, and the costs imposed on applicants by this regulatory action will be limited to paperwork burden related to preparing an application. The benefits of implementing the program—to assist SEAs in reforming and improving their systems for personnel preparation and professional development in early intervention, educational, and transition services in order to improve results for children with disabilities—will outweigh the costs incurred by applicants, and the costs of carrying out activities associated with the application will be paid for with program funds. For these reasons, we have determined that the costs of implementation will not be burdensome for eligible applicants, including small entities.

Paperwork Reduction Act of 1995

The final priority and definitions contain information collection requirements that are approved by OMB under OMB control number 1820–0028; the final priority and definitions do not affect the currently approved data collection.

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

The small entities that this final regulatory action will affect are SEAs of the 50 States, the District of Columbia, or the Commonwealth of Puerto Rico or an outlying area (United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands). We believe that the costs imposed on an applicant by the final priority and definitions will be limited to paperwork burden related to preparing an application and that the benefits of this final priority and these final definitions will outweigh any costs incurred by the applicant.

Participation in the SPDG program is voluntary. For this reason, the final priority and definitions will impose no burden on small entities unless they apply for funding under the program. We expect that in determining whether to apply for SPDG program funds, an eligible entity will evaluate the requirements of preparing an application and any associated costs, and weigh them against the benefits likely to be achieved by receiving an SPDG program grant. An eligible entity will probably apply only if it determines that the likely benefits exceed the costs of preparing an application.

We believe that the final priority and definitions will not impose any additional burden on a small entity applying for a grant than the entity would face in the absence of the final action. That is, the length of the applications those entities would submit in the absence of the final regulatory action and the time needed to prepare an application will likely be the same.

This final regulatory action will not have a significant economic impact on a small entity once it receives a grant because it would be able to meet the costs of compliance using the funds provided under this program.

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

This document provides early notification of our specific plans and actions for this program.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Mark Schultz,

Commissioner, Rehabilitation Services Administration, Delegated the authority to perform the functions and duties of the Assistant Secretary for the Office of Special Education and Rehabilitative Services.

[FR Doc. 2020–15983 Filed 7–27–20; 4:15 pm]

BILLING CODE 4000–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AQ63

Specialty Education Loan Repayment Program

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its regulations that govern scholarship programs to certain health care professionals. This rulemaking implements the mandates of the VA MISSION Act of 2018 by establishing a Specialty Education Loan Repayment Program, which will assist VA in meeting the staffing needs of VA physicians in medical specialties for which VA has determined that recruitment or retention of qualified personnel is difficult.

DATES: This rule is effective August 28, 2020.

FOR FURTHER INFORMATION CONTACT: Teresa Culpepper, Manager, Education Loan Repayment Services, 810 Vermont Avenue NW, Washington, DC 20420, (501) 687–4064. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On December 26, 2019, VA published a proposed rule in the **Federal Register** (84 FR 70908) that called for the establishment of a new student loan repayment program, the Specialty Education Loan Repayment Program (SELRP). VA provided a 60-day comment period, which ended on February 24, 2020. We received 4 comments on the proposed rule.

On June 6, 2018, section 303 of Public Law 115–182, the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018, or the VA MISSION Act of 2018, amended title 38 of the United States Code (U.S.C.) by establishing new sections 7691 through 7697 and created the SELRP. The SELRP serves as an incentive for physicians starting or currently in residency programs in medical specialties, for which VA has determined that recruitment and retention of qualified personnel is difficult, to work at VA facilities that need more physicians within that medical specialty after the individual completes their residency program. VA will determine the anticipated needs for medical specialties during a period of two to six years in the future. In taking this proactive approach, VA will commence recruitment for physicians in these specialties before the projected need to help ensure adequate health care coverage for VA beneficiaries. This final rule will establish the requirements for the SELRP in new 38 CFR 17.525 through 17.531.

One commenter requested that VA expand the individuals who qualify for the SELRP to include certified registered nurse anesthetists (CRNAs). The commenter stated that they understand there is underutilization and staffing shortages of other types of providers, including certified registered nurse anesthetists (CRNAs), and the commenter asked that this loan

repayment program be broadened to include incentives for recruitment and retention of advanced practice registered nurses (APRNs) in VA medical facilities. Another commenter similarly stated that to alleviate the primary care gap, a report recommends expanding the Primary Care Services Corps, which repays loans of nurse practitioners and physician assistants willing to work in underserved areas, and creating more Medicare-funded or state-funded residency slots for primary care doctors willing to work in upstate areas that need more physicians. Another commenter recommended that VA provide flexibility in the eligibility requirements to allow for fellows to be eligible. Fellows could also benefit from the program and may only have one year left of training. The current requirement for this program, however, limits participation to physicians currently in training who have more than two years remaining to complete such training. The commenter further added that fellows could deepen the applicant pool for the program, helping to facilitate participation by more psychiatrists during this time of critical need.

We agree with the commenters in that VA's shortage of health care professionals is not limited to physicians. However, 38 U.S.C. 7693 establishes the eligibility criteria for individuals who wish to participate in the SELRP. This criteria states that eligible individuals must be recently graduated from an accredited medical or osteopathic school and matched to an accredited residency program in a medical specialty described in section 7692 of this title; or a physician in training in a medical specialty described in section 7692 of this title with more than 2 years remaining in such training. As such, VA cannot extend the eligibility criteria to include individuals who are not otherwise listed in section 7692. We are not making any changes based on these comments.

A commenter requested that CRNAs be granted the ability to practice to the full scope of their education, training, licensure, and certification in VA medical facilities to allow veterans to receive access to safe and timely anesthesia services. The commenter stated that this step would make an anesthesia position within the VA more attractive in its own right to prior active duty and civilian CRNAs. The commenter's request that VA grant CRNAs full practice authority is beyond the scope of the proposed rule. We are not making any changes based on this comment.

Another commenter recommended expanding the Doctors Across New York, or DANY, program that, as one of its features, forgives up to $150,000 of student loan debt for young physicians who commit to practicing medicine in certain parts of the state for at least five years. The commenter stated that medical school graduates from the class of 2012 left school with an average student loan debt of $166,750, according to the Association of American Medical Colleges. The commenter added that in the most recent round of the DANY program, 26 young doctors in 2013 received the full, five-year awards. The SELRP is not a loan forgiveness program. Section 7494(c)(1) of 38 U.S.C. states that the amount of payments made for a participant under the SELRP may not exceed $160,000 over a total of four years of participation in the Program, of which not more than $40,000 of such payments may be made in each year of participation in the Program. If an individual participates in the SELRP for four years, the total amount of repayment of the individual's educational loan would be more than the $150,000 that the commenter stated that is repaid under the DANY. Also, VA does not have the statutory authority to adopt any provision of the DANY and any such adoption is beyond the scope of the proposed rule. We are not making any changes based on this comment.

Several comments proposed opening new physician or medical schools, with some comments offering a specific number of schools to be opened, and some comments offering specific reasons why such schools should be opened or current failings to open such schools. The opening of new physician or medical schools is beyond the scope of the proposed rule and is not within VA's authority to do under section 303 of Public Law 115–182. We are not making any changes based on these comments.

A commenter referred to a HANYS survey and stated that they agree with this survey in that the survey recommends greater use of telemedicine to allow certain specialists to remotely provide a consultation or other medical service to patients in underserved areas of the state. The commenter did not provide more details on the source of the survey or the date of the study, so we are not clear what this survey might refer or relate to. Although the provision of telehealth services is beyond the scope of the proposed rule, we generally respond that VA has regulations in place that grant VA health care professionals the ability to provide telehealth services, within their scope of practice, functional statement, and/or in accordance with privileges granted to them by VA, irrespective of the State or location within a State where the health care provider or the beneficiary is physically located. *See* 38 CFR 17.417. VA also has statutory authority under 38 U.S.C. 1730C for the provision of telehealth services by VA health care professionals. We are not making any changes based on this comment.

A commenter stated that incentives for medical students to pursue a career in primary care by helping with student loans is not enough to change what the commenter stated was a trend in which less than 10 percent of medical students are going into primary care. The commenter added that Medicare needs to restructure the reimbursement system now so current family practitioners, internists and pediatricians will have higher pay. The restructuring of Medicare's reimbursement system is beyond the scope of the proposed rulemaking. We are not making any changes based on this comment.

Another commenter indicated that they have long advocated for better recruitment of psychiatrists in the VA through the Clay Hunt Suicide Prevention for American Veterans Act, which included a pilot project encouraging more psychiatrists to choose a career with the VA by offering medical school loan repayments on par with those offered by other government agencies and private practices. The commenter added that the program was never implemented, but they are encouraged by the release of the SELRP and its potential to incentivize more psychiatrists to pursue careers with the VA. VA established into regulations the Program for the Repayment of Educational Loans for Certain VA Psychiatrists (PREL), which was established by Public Law 114–2, section 4, the Clay Hunt Suicide Prevention for American Veterans Act (Clay Hunt SAV Act). *See* 81 FR 66820, Sept. 29, 2016. VA is planning to implement the PREL in the near future and agrees with the commenter that the PREL will help alleviate the shortage of VA psychiatrists and increase veterans' access to needed mental health care. We are not making any changes based on this comment.

A commenter recommended that the SELRP be portable to sites where specialty is needed instead of the recipient being placed in one location. We believe the commenter intended to recommend that the SELRP be portable to VA facilities where a resident's specialty is needed, to enable rotations or other multiple assignments of such residents. As previously stated in this rulemaking, the SELRP serves as an

incentive for physicians starting or currently in residency programs in medical specialties for which VA has determined that recruitment and retention of qualified personnel is difficult, to work for VA at VA facilities that need more physicians with that medical specialty after the individual completes their residency program. VA will continuously monitor locations where there is the greatest need for physician specialties and appoint qualified individuals to these locations. To the extent the commenter recommends that VA enable rotations of residents in the SELRP, such administrative matters could be addressed outside of regulation and do not relate to the aspects of the SELRP that were proposed. We are not making any changes based on this comment.

A commenter stated that special protections or a continuation of eligibility should also be included for parental leave to encourage women to participate. The commenter added that given that this is early career, such protections are necessary to support applicants. The commenter also stated that Federal guidelines on parental leave should be followed as a minimum. VA agrees with the commenter. Because the participants of the SELRP are appointed VA employees, all Federal rules regarding parental leave apply. We are not making any changes based on this comment.

A commenter recommended that VA ensure that they coordinate with local VAs to announce and connect potential loan repayment recipients with local vacancies. The proposed rule stated in § 17.527(a)(1) that in determining staffing needs, VA will consider the anticipated needs of VA for a period of two to six years in the future. VA will publish these vacancies in a notice in the **Federal Register** on an annual basis until vacancies are filled. Also, under § 17.530(b)(2), VA will provide SELRP participants a list of qualifying medical facility locations from which a participant may select a service location. However, VA reserves the right to make final decisions on the location and position of the obligated service. All placements will be coordinated and verified with local VA medical centers, including preliminary identification position need and medical center participation through selection and placement of eligible candidates. We are not making any changes based on this comment.

A commenter also recommended that VA develop a process to comprehensively evaluate and track the application and placement process for accountable and equitable disbursement among the applicants, to ensure that psychiatrists are receiving equivalent consideration for this program among the specialties. The commenter added that this process could also include a mechanism to ensure the application process is not too burdensome for prospective candidates, thus streamlining the process overall. VA is leveraging existing programs and technologies to meet the lengthy application requirements while minimizing redundant requests for information. For example, VA will utilize approved VA forms to collect personnel and job application information instead of creating new program forms. We are not making any changes based on this comment.

We are making technical edits to § 17.529(c)(2)(i) for clarity. Proposed § 17.528(c)(2)(i) stated that a summary of the applicant's educational debt, which includes the total debt amount and when the debt was acquired, would be one piece of information that must be provided to VA. Proposed § 17.528(c)(2)(i) further stated that the health professional debt covered the loan must be specific to education that was required, used, and qualified the applicant for appointment as a physician. We have amended this paragraph to now state a summary of the applicant's educational loan, which includes the total loan amount and when the loan was acquired. The educational loan must be specific to the education that was required and used to qualify the applicant for appointment as a physician. VA always intended the meaning of the educational loan in this paragraph to clearly state that the eligible loan would only be that which was required and used to qualify an applicant for the SELRP. This change does not result in any substantive change in meaning and is only intended to be a technical change.

Based on the rationale set forth in the Supplementary Information to the proposed rule and in this final rule, VA is adopting the proposed rule with the edits discussed in this rule.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (at 44 U.S.C. 3507) requires that VA consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number. This rule includes provisions constituting new collections of information under the Paperwork Reduction Act of 1995 that require approval by the OMB. Accordingly, under 44 U.S.C. 3507(d), VA has submitted a copy of this rulemaking action to OMB for review.

38 CFR 17.528 contains collections of information under the Paperwork Reduction Act of 1995. If OMB does not approve the collections of information as requested, VA will immediately remove the provisions containing a collection of information or take such other action as is directed by the OMB.

The collections of information contained in 38 CFR 17.528 are described immediately following this paragraph.

Title: Specialty Education Loan Repayment Program.

Summary of collection of information: The information required determines the eligibility or suitability of an applicant desiring to participate in the SELRP under the provisions of 38 U.S.C. 7691 through 7697. The purpose of the SELRP would be to repay educational loans to individuals who pursued a program of study leading to a degree in medicine and who are seeking employment in VA. VA considers this program as a hiring incentive to meet the staffing needs for physicians in medical specialties for which VA determines that recruitment and retention of qualified personnel is difficult.

Description of the need for information and proposed use of information: The information is needed to apply for the SELRP. VA will use this information to select qualified candidates to participate in this program.

Description of likely respondents: Potential participants of the SELRP.

Estimated number of respondents per month/year: 200 per year.

Estimated frequency of responses per month/year: 1 time per year.

Estimated average burden per response: 90 minutes.

Estimated total annual reporting and recordkeeping burden: 80 hours.

Estimated cost to respondents per year: VA estimates the total cost to all respondents to be $8,130 per year.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The provisions associated with this rulemaking are not processed by any other entities outside of VA. Therefore, pursuant to 5 U.S.C.

605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Executive Orders 12866, 13563 and 13771

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866.

VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's website at *http://www.va.gov/orpm/,* by following the link for ''VA Regulations Published From FY 2004 Through Fiscal Year to Date.''

This final rule is not expected to be an E.O. 13771 regulatory action because this final rule is not significant under E.O. 12866.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Congressional Review Act

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

Catalog of Federal Domestic Assistance

There are no Catalog of Federal Domestic Assistance numbers and titles for this rule.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Health care, Health facilities, Health professions, Health records, Medical and dental schools, Scholarships and fellowships, Veterans.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Brooks D. Tucker, Acting Chief of Staff, Department of Veterans Affairs, approved this document on July 13, 2020, for publication.

Consuela Benjamin,

Regulations Development Coordinator, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs amends 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 is amended as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

* * * * *

Sections 17.525 through 17.531 are also issued under 38 U.S.C. 7691 through 7697.

* * * * *

■ 2. Adding an undesignated center heading immediately following § 17.511 and new §§ 17.525 through 17.531 to read as follows.

Specialty Education Loan Repayment Program

Sec.

§ 17.525 Purpose.

The purpose of §§ 17.525 through 17.531 is to establish the Specialty Education Loan Repayment Program (SELRP). The SELRP is an incentive program for certain individuals to meet VA's need for physicians in medical specialties for which VA determines that recruitment and retention of qualified personnel is difficult. Assistance under the SELRP may be in addition to other assistance available to individuals under the Educational Assistance Program under 38 U.S.C. 7601.

§ 17.526 Definitions.

The following definitions apply to §§ 17.525 through 17.530:

Educational loan means a loan, government or commercial, made for educational purposes by institutions that are subject to examination and supervision in their capacity as lending institutions by an agency of the United States or of the state in which the lender has its principal place of business. Loans must be for the actual costs paid for tuition, and other reasonable educational expenses such as living expenses, fees, books, supplies, educational equipment and materials, and laboratory expenses. Loans must be obtained from a government entity, a private financial institution, a school, or any other authorized entity stated in this definition. The following loans do not qualify for the SELRP:

(1) Loans obtained from family members, relatives, or friends;

(2) Loans made prior to, or after, the individual's qualifying education;

(3) Any portion of a consolidated loan that is not specifically identified with the education and purposes for which the SELRP may be authorized, such as home or auto loans merged with educational loans;

(4) Loans for which an individual incurred a service obligation for repayment or agreed to service for future cancellation;

(5) Credit card debt;

(6) Parent Plus Loans;

(7) Loans that have been paid in full;

(8) Loans that are in default, delinquent, not in a current payment status, or have been assumed by a collection agency;

(9) Loans not obtained from a bank, credit union, savings and loan association, not-for-profit organization, insurance company, school, and other financial or credit institution which is subject to examination and supervision in its capacity as a lending institution by an agency of the United States or of the state in which the lender has its principal place of business;

(10) Loans for which supporting documentation is not available;

(11) Loans that have been consolidated with loans of other individuals, such as spouses, children, friends, or other family member; or

(12) Home equity loans or other noneducational loans.

SELRP means the Specialty Education Loan Repayment Program established in §§ 17.525 through 17.530.

State means a State as defined in 38 U.S.C. 101(20), or a political subdivision of such a State.

VA means the Department of Veterans Affairs.

§ 17.527 Eligibility.

(a) *General.* An individual must meet the following requirements to be eligible to participate in the SELRP:

(1) Will be eligible for appointment under 38 U.S.C. 7401 to work as a physician in a medical specialty for which VA determines that recruitment or retention of qualified personnel is difficult. In determining staffing needs, VA will consider the anticipated needs of VA for a period of two to six years in the future. VA will publish these vacancies in a notice in the **Federal Register** on a yearly basis until vacancies are filled.

(2) Owes any amount of principal or interest for an educational loan where the proceeds were used by or on behalf of the individual to pay costs relating to a course of medical education or training that leads to employment as a physician and;

(3) Is:

(i) Recently graduated from an accredited medical or osteopathic school and matched to an accredited residency program in a medical specialty designated by VA; or

(ii) A physician in training with more than 2 years remaining in such training.

(b) *Applicants without a residency match.* An applicant may apply for the SELRP before receiving a residency match during the applicant's senior year of medical or osteopathic school. Once the applicant is matched with a residency specialty stated in § 17.525 and upon selection of the SELRP, VA must offer the applicant participation in the SELRP no later than 28 days after:

(1) The applicant is matched with the residency; and

(2) VA has published the residency in a Notice in the **Federal Register**. Such notices are published on a yearly basis until vacancies are filled.

(c) *Preferences.* VA will give preference to eligible participants who:

(1) Are, or will be, participating in residency programs in health care facilities that are:

(i) Located in rural areas;

(ii) Operated by Indian tribes, tribal organizations, or the Indian Health Services; or

(iii) Are affiliated with underserved health care facilities of VA; or

(2) Veterans.

§ 17.528 Application.

(a) *General.* A complete application for the SELRP consists of a completed application form, letters of reference, and personal statement.

(b) *References.* The applicant must provide the following letters of reference and sign a release of information form for VA to contact such references:

(1) One letter of reference from the Program Director of the core program in which the applicant is training, which indicates that the applicant is in good to excellent standing, or, for individuals who have yet to initiate training, a letter of reference from a faculty member or dean;

(2) One or more letters of reference from faculty members under which the applicant trained; and

(3) One letter of reference from a peer colleague who is familiar with the practice and character of the applicant.

(c) *Personal statement.* The personal statement must include the following documentation:

(1) A cover letter that provides the following information:

(i) Why the applicant is interested in VA employment;

(ii) The applicant's interest in working at a particular medical specialty and underserved area;

(iii) Likely career goals, including career goals in VA; and

(iv) A brief summary of past employment or training and accomplishments, including any particular clinical areas of interest (*e.g.,* substance abuse).

(2) The following information must be provided on a VA form or online collection system and is subject to VA verification:

(i) A summary of the applicant's educational loan, which includes the total loan amount and when the loan was acquired. The educational loan must be specific to the education that was required and used to qualify the applicant for appointment as a physician.

(ii) The name of the lending agency that provided the educational loan.

(3) A full curriculum vitae.

(The Office of Management and Budget has approved the information collection requirements in this section under control number XXXX–XXXX.)

§ 17.529 Award procedures.

(a) *Repayment amount.* (1) VA may pay no more than $40,000 in educational loan repayment for each year of obligated service for a period not to exceed four years for a total payment of $160,000.00.

(2) An educational loan repayment may not exceed the actual amount of principal and interest on an educational loan or loans.

(b) *Payment.* VA will pay the participant, or the lending institution on behalf of the participant, directly for the principal and interest on the participant's educational loans. Payments will be made monthly or annually for each applicable service period, depending on the terms of the agreement. Participants must provide VA documentation that shows the amounts that were credited or posted by the lending institution to a participant's educational loan during an obligated service period. VA will issue payments after the participant commences the period of obligated service. Payments are exempt from Federal taxation.

(c) *Waiver of maximum amount of payment.* VA may waive the limitations under paragraph (a)(1) of this section to participants of the SELRP if VA determines that there is a shortage of qualified employees due to either the location of where the participant will serve the period of obligated service or the requirements of the position that the participant will hold in VA. However, the waiver may not exceed the actual amount of the principal and the interest on the participant's loans payable to or for that participant.

§ 17.530 Agreement and obligated service.

(a) *General.* In addition to any requirements under section 5379(c) of title 5, a participant in the SELRP must agree, in writing, to the following:

(1) Obtain a license to practice medicine in a State;

(2) Successfully complete postgraduate training leading to eligibility for board certification in a medical specialty;

(3) Serve as a full-time clinical practice employee of VA for 12 months for every $40,000.00 that the participant receives payment through the SELRP, however, the participant must serve for a period of no fewer than 24 months; and

(4) Except as provided in paragraph (b) of this section, begin obligated service as a full-time VA employee no later than 60 days after completing residency in the medical specialty described in § 17.527(a)(1).

(b) *Obligated service.* (1) *General provision.* A participant's obligated service will begin on the date on which the participant begins full-time permanent employment with VA in the qualifying field of medicine in a location determined by VA. Obligated service must be full-time permanent employment and does not include any period of temporary or contractual employment.

(2) *Location and position of obligated service.* VA will provide SELRP participants a list of qualifying medical facility locations. A participant may select a service location from that list.

However, VA reserves the right to make final decisions on the location and position of the obligated service.

(c) *Exception to commencement of obligated service.* If a participant receives an accredited fellowship in a medical specialty other than the specialty described in § 17.27(a)(1), the participant may request, in writing, a delayed commencement of the period of obligated service until after the participant completes the fellowship. However, the period of obligated service will begin no later than 60 days after completion of such fellowship in the medical specialty described in § 17.527(a)(1).

§ 17.531 Failure to comply with terms and conditions of agreement.

A participant of the SELRP who fails to satisfy the period of obligated service will owe the United States government an amount determined by the formula $A = B \times ((T - S) \div T)$, where:

(a) ''A'' is the amount the participant owes the United States government.

(b) ''B'' is the sum of all payments to or for the participant under the SELRP.

(c) ''T'' is the number of months in the period of obligated service of the participant.

(d) ''S'' is the number of whole months of such period of obligated service served by the participant.

[FR Doc. 2020–15411 Filed 7–28–20; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2019–0541; FRL–10012–17–Region 9]

Clean Air Plans; 2008 8-Hour Ozone Nonattainment Area Requirements; Phoenix-Mesa, Arizona; Correcting Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Correcting amendment.

SUMMARY: On June 2, 2020, the Environmental Protection Agency (EPA) issued a final rule entitled ''Clean Air Plans; 2008 8-Hour Ozone Nonattainment Area Requirements; Phoenix-Mesa, Arizona.'' That publication inadvertently omitted from the regulatory text the disapproval of the portion of the ''MAG 2017 Eight-Hour Ozone Moderate Area Plan for the Maricopa Nonattainment Area (December 2016)'' (''MAG 2017 Ozone Plan'') that addresses the requirements for contingency measures for failure to attain or to make reasonable further progress (RFP). This document corrects this error in the regulatory text.

DATES: This rule is effective on July 29, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2019–0541. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information 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: Nancy Levin, EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105. Phone: (415) 972–3848 or by email at *levin.nancy@epa.gov.*

SUPPLEMENTARY INFORMATION: On June 2, 2020, the Environmental Protection Agency (EPA) issued a final rule entitled ''Clean Air Plans; 2008 8-Hour Ozone Nonattainment Area Requirements; Phoenix-Mesa, Arizona.'' That publication inadvertently omitted from the regulatory text the disapproval of the portion of the MAG 2017 Ozone Plan that addresses the requirements for contingency measures for failure to attain or to make RFP. This action corrects the omission in Section 52.120 table 1.

The EPA has determined that this action falls under the ''good cause'' exemption in section 553(b)(3)(B) of the Administrative Procedure Act (APA) which, upon finding ''good cause,'' authorizes agencies to dispense with public participation where public notice and comment procedures are impracticable, unnecessary, or contrary to the public interest. Public notice and comment for this action is unnecessary because the underlying rule for which this correcting amendment has been prepared was already subject to a 30-day comment period, and this action is merely correcting a minor typographical error in the rule text. Further, this action is consistent with the purpose and rationale of the final rule, which is corrected herein. Because this action does not change the EPA's analyses or overall actions, no purpose would be served by additional public notice and comment. Consequently, additional public notice and comment are unnecessary.

The EPA also finds that there is good cause under APA section 553(d)(3) for this correction to become effective on the date of publication of this action. Section 553(d)(3) of the APA allows an effective date of less than 30 days after publication ''as otherwise provided by the agency for good cause found and published with the rule.'' 5 U.S.C. 553(d)(3). The purpose of the 30-day waiting period prescribed in APA section 553(d)(3) is to give affected parties a reasonable time to adjust their behavior and prepare before the final rule takes effect. This rule does not create any new regulatory requirements such that affected parties would need time to prepare before the rule takes effect. This action merely corrects a typographical error in a previous rulemaking. For these reasons, the EPA finds good cause under APA section 553(d)(3) for this correction to become effective on the date of publication of this action.

Statutory and Executive Order Reviews

Under Executive Order (E.O.) 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to E.O. 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action is not an E.O. 13771 (82 FR 9339, February 2, 2017) regulatory action because this action is not significant under E.O. 12866. Because the agency has made a ''good cause'' finding that this action is not subject to notice-and-comment requirements under the Administrative Procedures Act or any other statute as indicated in the Supplementary Information section above, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA. In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal

governments or preempt tribal law as specified by E.O. 13175 (65 FR 67249, November 9, 2000). This rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of governments, as specified by E.O. 13132 (64 FR 43255, August 10, 1999). This rule also is not subject to E.O. 13045 (62 FR 19885, April 23, 1997), because it is not economically significant. This typographical correction action does not involve technical standards; thus the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. The rule also does not involve special consideration of environmental justice related issues as required by E.O. 12898 (59 FR 7629, February 16, 1994). In issuing this rule, the EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of E.O. 12988 (61 FR 4729, February 7, 1996). The EPA has complied with E.O. 12630 (53 FR 8859, March 15, 1998) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, the EPA had made such a good cause finding, including the reasons therefore, and established an effective date of July 29, 2020. The 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 correction to 40 CFR part 52 for Arizona is not a ''major rule'' as defined by 5 U.S.C. 804(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.

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

Dated: July 15, 2020.

John Busterud,

Regional Administrator, Region IX.

For the reasons stated in the preamble, EPA corrects Part 52, Chapter I, Title 40 of the Code of Federal Regulations by making the following correcting amendments:

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 D—Arizona

■ 2. In § 52.120 amend table 1 in paragraph (e), under the heading ''Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas,'' by removing the entry reading ''MAG 2017 Eight-Hour Ozone Moderate Area Plan for the Maricopa Nonattainment Area (December 2016)'', and adding in its place in the table, an entry for ''MAG 2017 Eight-Hour Ozone Moderate Area Plan for the Maricopa Nonattainment Area (December 2016) and appendices, excluding the contingency measure element'' to read as follows:

§ 52.120 Identification of plan.

* * * * *

(e) * * *

TABLE 1—EPA-APPROVED NON-REGULATORY AND QUASI-REGULATORY MEASURES

[Excluding certain resolutions and statutes, which are listed in tables 2 and 3, respectively] [1]

Name of SIP provision	Applicable geographic or nonattainment area or title/subject	State submittal date	EPA approval date	Explanation
The State of Arizona Air Pollution Control Implementation Plan				
* *	* *	* *	*	*
MAG 2017 Eight-Hour Ozone Moderate Area Plan for the Maricopa Nonattainment Area (December 2016) and appendices, excluding the contingency measure element.	Phoenix-Mesa 2008 8-hour ozone nonattainment area.	December 19, 2016.	[INSERT **Federal Register** CITATION], 7/29/2020.	Adopted by the Arizona Department of Environmental Quality by letter dated December 13, 2016. EPA approved all elements except the contingency measure element.
* *	* *	* *	*	*

[1] Table 1 is divided into three parts: Clean Air Act Section 110(a)(2) State Implementation Plan Elements (excluding Part D Elements and Plans), Part D Elements and Plans (other than for the Metropolitan Phoenix or Tucson Areas), and Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas.

* * * * *

[FR Doc. 2020–15699 Filed 7–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2017–0105; FRL–10012–12–Region 4]

Air Plan Approval; Florida: Public Notice Procedures for Minor Operating Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve portions of a State Implementation Plan (SIP) revision submitted by the State of Florida, through the Florida Department of Environmental Protection (FDEP), on February 27, 2013. These portions change the State's public notice and comment rule for air permitting by modifying the length of the public comment period for minor source operating permitting and by making non-substantive edits.

DATES: This rule is effective August 28, 2020.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2017–0105. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information 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 can either be retrieved electronically via *www.regulations.gov*, or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: D. Brad Akers, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Mr. Akers can be reached via telephone at (404) 562–9089 or via electronic mail at *akers.brad@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

EPA is approving changes to the Florida SIP that were provided to EPA through FDEP via a letter dated February 27, 2013.[1] EPA has previously approved portions of the February 27, 2013 submittal,[2] and FDEP has withdrawn other portions from EPA consideration.[3] EPA is approving the remaining portions of this SIP revision. These remaining portions make changes to Rule 62–210.350, Florida Administrative Code (F.A.C.), *Public Notice and Comment,* by revising the length of the public notice period required for federally enforceable state operating permits (FESOPs) from 30 days to 14 days and making several minor non-substantive edits to the Rule. FESOPs are federally enforceable permits issued by a state under a minor source operating permit program that EPA has approved into the SIP as meeting criteria published by the Agency on June 28, 1989. *See* 54 FR 27274 (June 28, 1989) (hereinafter FESOP Guidance). See EPA's May 5, 2020, notice of proposed rulemaking (NPRM) (85 FR 26641) for further details on these changes and EPA's rationale for approving them.

Comments on the NPRM were due on or before June 4, 2020, and EPA received one comment. EPA has summarized this comment and is providing a response in the following section. The complete comment is available in the docket for this rulemaking.

II. Response to Comment

Comment: The Commenter requests that EPA confirm that the 14-day comment period at Rule 62–210.350 for FESOP minor source permits will not be followed if the minor source permit is going to be used for SIP purposes. The Commenter further states that should such a FESOP minor source permit need to be approved into the SIP, EPA must clarify that a 30-day public comment period is required.

Response: The 14-day comment period in Rule 62–210.350 applies to the issuance of all FESOPs regardless of whether the State will ultimately submit them to EPA for incorporation into the SIP. As discussed in the NPRM, there are no specific public notice requirements for the issuance of minor source operating permits in the Clean Air Act (CAA) or implementing regulations, and Florida's rule complies with EPA's FESOP Guidance. The Commenter does not challenge this rationale for approving the SIP revision or explain why FESOPs submitted for SIP purposes must undergo a 30-day comment period prior to issuance.[4]

Nonetheless, all SIP submittals, including those that contain permit conditions for incorporation into the SIP, must undergo a 30-day public comment period at the state level pursuant to CAA Section 110(a), 40 CFR 51.102, and Appendix V to 40 CFR part 51, *Criteria for Determining the Completeness of Plan Submissions.* This comment period is separate from and in addition to the comment period on any permits included in that submittal. Furthermore, EPA must provide for public comment when proposing to approve a SIP submittal unless, for good cause, it finds that a public comment period is impracticable, unnecessary, or contrary to the public interest. *See* 5 U.S.C. 553. The public therefore has ample opportunity to submit comments on a SIP submittal. If the submittal seeks to incorporate permit conditions into the SIP, the public can comment during the state and federal public comment periods regarding the sufficiency of those conditions for SIP purposes.

III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of Rule 62–210.350, F.A.C., *Public Notice and Comment,* state effective October 12, 2008, consisting of changes to the public comment period regarding FESOPs as well as non-

[1] EPA received the submittal on March 6, 2013.

[2] EPA approved portions of the February 27, 2013, SIP revision making changes to Rule 62–210.200, *Definitions,* 62–210.310, *Air General Permits,* and portions of 62–210.350, *Public Notice and Comment,* specifically portions of 62–210.350(1) and (4), on October 6, 2017 (82 FR 46682).

[3] FDEP withdrew portions of the February 27, 2013, SIP revision as follows: FDEP withdrew certain changes to Rule 62–210.200, *Definitions,* Rule 62–210.350, *Public Notice and Comment,* and Rule 62–296.401, *Incinerators,* on June 28, 2017; and FDEP withdrew the changes to 62–210.300, *Permits Required,* on December 5, 2019. These letters are located in the docket for this rulemaking.

[4] As discussed in the NPRM, even with the revision to Rule 62.210.350, the State may provide for a longer comment period on FESOPs when a commenter requests an extension.

substantive edits.[5] EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the State implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[6]

IV. Final Action

EPA is approving changes to the Florida SIP included in a February 27, 2013, submittal. Specifically, EPA is approving changes to the public comment period regarding FESOPs, as well as non-substantive edits, in Rule 62–210.350, F.A.C., *Public Notice and Comment,* state effective October 12, 2008. EPA is approving these changes because they are not inconsistent with the FESOP Guidance or the CAA, and because the changes will not interfere with any applicable requirement concerning attainment and reasonable further progress or any other requirements in the Act.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. 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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- 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).

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 as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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 September 28, 2020. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: July 15, 2020.

Mary Walker,

Regional Administrator, Region 4.

Therefore, 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 K—Florida

■ 2. In § 52.520 amend the table in paragraph (c) by revising the entry for ''62–210.350'' to read as follows:

§ 52.520 Identification of plan.

* * * * *

(c) * * *

[5] Except for 62–210.350(1)(c) which was withdrawn from EPA consideration on June 28, 2017.

[6] *See* 62 FR 27968 (May 22, 1997).

EPA APPROVED FLORIDA REGULATIONS

State citation (section)	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	* * *
Chapter 62–210 Stationary Sources—General Requirements				
*	*	*	*	* * *
62–210.350	Public Notice and Comment.	10/12/2008	07/29/2020 [Insert citation of publication].	Except for 62–210.350(1)(c) which was withdrawn from EPA consideration on June 28, 2017.
*	*	*	*	* * *

* * * * *

[FR Doc. 2020–15700 Filed 7–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2019–0612; FRL–10012–02–Region 4]

Air Plan Approval; SC; NO_X SIP Call and Removal of CAIR

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving State Implementation Plan (SIP) revisions submitted by the State of South Carolina through letters dated April 12, 2019, and July 11, 2019, to establish a SIP-approved state control program to comply with the Nitrogen Oxides (NO_X) SIP call obligations for electric generating units (EGUs) and large non-EGUs. EPA is also approving the removal of the SIP-approved portions of the State's Clean Air Interstate Rule (CAIR) Program rules from the South Carolina SIP. In addition, EPA is approving into the SIP state regulations that establish an alternative monitoring option for certain sources.

DATES: This rule is effective August 28, 2020.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2019–0612. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information 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 can either be retrieved electronically via *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Gobeail McKinley, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9230. Ms. McKinley can also be reached via electronic mail at *mckinley.gobeail@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under Clean Air Act (CAA or Act) section 110(a)(2)(D)(i)(I), which EPA has traditionally termed the good neighbor provision, states are required to address the interstate transport of air pollution. Specifically, the good neighbor provision requires that each state's implementation plan contain adequate provisions to prohibit air pollutant emissions from within the state that will significantly contribute to nonattainment of the national ambient air quality standards (NAAQS), or that will interfere with maintenance of the NAAQS, in any other state.

In October 1998 (63 FR 57356), EPA finalized the ''Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone'' (''NO_X SIP Call''). The NO_X SIP Call required eastern states, including South Carolina, to submit SIPs that prohibit excessive emissions of ozone season NO_X by implementing statewide emissions budgets.[1] The NO_X SIP Call addressed the good neighbor provision for the 1979 ozone NAAQS and was designed to mitigate the impact of transported NO_X emissions, one of the precursors of ozone. EPA developed the NO_X Budget Trading Program, an allowance trading program that states could adopt to meet their obligations under the NO_X SIP Call. This trading program allowed the following sources to participate in a regional cap and trade program: Generally EGUs with capacity greater than 25 megawatts (MW); and large industrial non-EGUs, such as boilers and combustion turbines, with a rated heat input greater than 250 million British thermal units per hour (MMBtu/hr). The NO_X SIP Call also identified potential reductions from cement kilns and stationary internal combustion engines.

To comply with the NO_X SIP Call requirements, South Carolina Department of Health and Environmental Control (SC DHEC) promulgated provisions at Regulation 61–62.96, Subparts A through I. EPA approved the provisions into South Carolina's SIP in 2002.[2] The provisions required EGUs and large non-EGUs in the State to participate in the NO_X Budget Trading Program.

In 2005, EPA published CAIR, which required eastern states, including South Carolina, to submit SIPs that prohibited

[1] *See* 63 FR 57356 (October 27, 1998). As originally promulgated, the NO_X SIP Call also addressed good neighbor obligations under the 1997 8-hour ozone NAAQS, but EPA subsequently stayed and later rescinded the rule's provisions with respect to that standard. *See* 65 FR 56245 (September 18, 2000); 84 FR 8422 (March 8, 2019).

[2] *See* 67 FR 43546 (June 28, 2002).

emissions consistent with ozone season (and annual) NO_X budgets. *See* 70 FR 25162 (May 12, 2005). CAIR addressed the good neighbor provision for the 1997 ozone NAAQS and 1997 fine particulate matter ($PM_{2.5}$) NAAQS and was designed to mitigate the impact of transported NO_X emissions with respect to not only ozone but also $PM_{2.5.}$ CAIR established several trading programs that EPA implemented through Federal implementation plans (FIPs) for EGUs greater than 25 MW in each affected state, but not large non-EGUs; states could submit SIPs to replace the FIPs that achieved the required emission reductions from EGUs and/or other types of sources.[3] When the CAIR trading program for ozone season NO_X was implemented beginning in 2009, EPA discontinued administration of the NO_X Budget Trading Program; however, the requirements of the NO_X SIP Call continued to apply.

On October 9, 2007, EPA approved an ''abbreviated SIP'' for South Carolina, consisting of regulations governing allocation of NO_X allowances to EGUs for use in the trading programs established pursuant to CAIR, and related rules allowing additional sources to opt into the CAIR programs. *See* 72 FR 57209. The abbreviated SIP was implemented in conjunction with a FIP for South Carolina that specified requirements for emissions monitoring, permit provisions, and other elements of CAIR programs.

On October 16, 2009, EPA approved a ''full SIP'' for South Carolina, through which various CAIR implementation provisions became governed by State rules rather than Federal rules.[4] Consistent with CAIR's requirements, EPA approved a SIP revision in which South Carolina regulations: (1) Sunsetted its NO_X Budget Trading Program requirements, (2) removed NO_X SIP Call implementation requirements (*i.e.,* South Carolina Regulation 61–62.96, Subparts A through I, ''Nitrogen Oxides (NO_X) Budget Program''), and (3) incorporated CAIR (*i.e.,* South Carolina Regulation 61–62.96, Subparts AA through II, AAA through III, and AAAA through IIII, ''Nitrogen Oxides (NO_X) and Sulfur Dioxide (SO_2) Budget Trading Program''). *See* 74 FR 53167 (October 16, 2009). Participation of EGUs in the CAIR ozone season NO_X trading program addressed the State's obligation under the NO_X SIP Call for those units, and South Carolina also chose to require non-EGUs subject to the NO_X SIP Call to participate in the same CAIR trading program. In this manner, South Carolina's CAIR rules incorporated into the SIP addressed the State's obligations under the NO_X SIP Call with respect to both EGUs and non-EGUs.

The United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) initially vacated CAIR in 2008, but ultimately remanded the rule to EPA without vacatur to preserve the environmental benefits provided by CAIR. *See North Carolina* v. *EPA,* 531 F.3d 896, *modified on rehearing,* 550 F.3d 1176 (D.C. Cir. 2008). The ruling allowed CAIR to remain in effect temporarily until a replacement rule consistent with the court's opinion was developed. While EPA worked on developing a replacement rule, the CAIR program continued to be implemented with the NO_X annual and ozone season trading programs beginning in 2009 and the SO_2 annual trading program beginning in 2010.

Following on the D.C. Circuit's remand of CAIR, EPA promulgated the Cross-State Air Pollution Rule (CSAPR) to replace CAIR and address the good neighbor provisions for the 1997 ozone NAAQS, the 1997 $PM_{2.5}$ NAAQS, and the 2006 $PM_{2.5}$ NAAQS. *See* 76 FR 48208 (August 8, 2011). Through FIPs, CSAPR required EGUs in eastern states, including South Carolina, to meet annual and ozone season NO_X emission budgets and annual SO_2 emission budgets implemented through new trading programs. Implementation of CSAPR began in January 1, 2015.[5] CSAPR also contained provisions that would sunset CAIR-related obligations on a schedule coordinated with the implementation of the CSAPR compliance requirements. Participation by a state's EGUs in the CSAPR trading program for ozone season NO_X generally addressed the state's obligation under the NO_X SIP Call for EGUs. CSAPR did not initially contain provisions allowing states to incorporate large non-EGUs into that trading program to meet the requirements of the NO_X SIP Call for non-EGUs. EPA also stopped administering CAIR trading programs with respect to emissions occurring after December 31, 2014.[6]

After litigation that reached the Supreme Court, the D.C. Circuit generally upheld CSAPR but remanded several state budgets to EPA for reconsideration, including the Phase 2 ozone season NO_X budget for South Carolina. *EME Homer City Generation, L.P.* v. *EPA,* 795 F.3d 118, 129–30 (D.C. Cir. 2015). EPA addressed the remanded ozone season NO_X budgets in the CSAPR Update, which also partially addressed eastern states' good neighbor obligations for the 2008 ozone NAAQS. *See* 81 FR 74504 (October 26, 2016). The air quality modeling for the CSAPR Update projected that South Carolina would not contribute significantly to nonattainment or interfere with maintenance in downwind areas for either the 1997 ozone NAAQS or the 2008 ozone NAAQS as of 2017, and the EGUs in the state therefore are no longer subject to a NO_X ozone season trading program under either CSAPR or the CSAPR Update.[7] The CSAPR Update also reestablished an option for most states to meet their ongoing obligations for non-EGUs under the NO_X SIP Call by including the units in the CSAPR Update trading program, but since South Carolina's EGUs do not participate in that trading program, the option is not available to South Carolina. Because South Carolina's EGUs and non-EGUs no longer participate in any CSAPR or CSAPR Update trading program for ozone season NO_X emissions, the NO_X SIP Call regulations at 40 CFR 51.121(r)(2) as well as anti-backsliding provisions at 40 CFR 51.905(f) and 40 CFR 51.1105(e) require these sources to maintain compliance with NO_X SIP Call requirements in some other way.

Under 40 CFR 51.121(i)(4) of the NO_X SIP Call regulations as originally promulgated, where a state's SIP contains control measures for EGUs and large non-EGUs, the SIP must also require these sources to monitor emissions according to the provisions of 40 CFR part 75, which generally entail the use of continuous emission monitoring systems (CEMS). South

[3] CAIR had separate trading programs for annual sulfur dioxide emissions, seasonal NO_X emissions and annual NO_X emissions.

[4] *See* 74 FR 53167.

[5] *See* 79 FR 71663 (December 3, 2014) and 81 FR 13275 (March 14, 2016).

[6] *See* 79 FR 71663 (December 3, 2014) and 81 FR 13275 (March 14, 2016).

[7] In the CSAPR Update, EPA relieved EGUs in South Carolina from the obligation to participate in the original CSAPR NO_X ozone season trading program for purposes of addressing the good neighbor requirements for the 1997 ozone NAAQS and did not require the EGUs to participate in the new CSAPR Update trading program for purposes of addressing the 2008 ozone NAAQS. *See* 40 CFR 52.38(b)(2)(ii)–(iii). EGUs in South Carolina remain subject to CSAPR state trading programs for annual NO_X and SO_2 emissions for purposes of addressing the $PM_{2.5}$ NAAQS under the state trading program rules codified in South Carolina regulation 61–62.97 that were adopted into the State's SIP. *See* 82 FR 47936. EPA acknowledges the D.C. Circuit's decision in *Wisconsin* v. *EPA,* 938 F.3d 303 (Sept. 13, 2019), remanding the CSAPR Update with respect to the adequacy of the rulemaking to address the good neighbor obligations with respect to the 2008 ozone NAAQS; however, the court's decision does not address the determinations made in the CSAPR Update regarding state's obligations with respect to the 1997 ozone NAAQS as those determinations were not challenged in the course of the litigation.

Carolina triggered this requirement by including control measures in their SIP for these types of sources, and the requirement has remained in effect despite the discontinuation of the NO_X Budget Trading Program after the 2008 ozone season. On March 8, 2019, EPA revised some of the regulations that were originally promulgated in 1998 to implement the NO_X SIP Call.[8] The revision gave states covered by the NO_X SIP Call greater flexibility concerning the form of the NO_X emissions monitoring requirements that the states must include in their SIPs for certain emissions sources. The revision amends 40 CFR 51.121(i)(4) to make part 75 monitoring, recordkeeping, and reporting optional, such that SIPs may establish alternative monitoring requirements for NO_X SIP Call budget units that meet the general requirements of 40 CFR 51.121(f)(1) and (i)(1). Under the updated provision, a state's implementation plan would still need to include some form of emissions monitoring requirements for these types of sources, consistent with the NO_X SIP Call's general enforceability and monitoring requirements at § 51.121(f)(1) and (i)(1), respectively, but states would no longer be required to satisfy these general NO_X SIP Call requirements specifically through the adoption of 40 CFR part 75 monitoring requirements.

On April 12, 2019, and July 11, 2019,[9] SC DHEC's letters requested that EPA update South Carolina's SIP to reflect the reinstated NO_X SIP Call requirements at Regulation 61–62, ''Air Pollution Control Regulations and Standards,'' provide additional monitoring flexibilities for certain units subject to the State's NO_X SIP Call regulations, and remove CAIR requirements. Additionally, the July 11, 2019, submission includes a demonstration under CAA section 110(l) intended to show that the April 12, 2019 SIP revision does not interfere with any applicable CAA requirements. On May 5, 2020 (85 FR 26635), EPA published a notice of proposed rulemaking (NPRM) proposing to establish a SIP-approved state control program to comply with NO_X SIP call obligations for EGUs and large non-EGUs. EPA also proposed approving the removal of the SIP-approved portions of the CAIR Program rules from the South Carolina SIP and approve into the SIP state regulations that establish an alternative monitoring option for certain sources.

See EPA's May 5, 2020 (85 FR 26635), NPRM for further detail on these changes and EPA's rationale for approving them. EPA did not receive public comments on the May 5, 2020, NPRM.

II. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of South Carolina Regulation 61–62.96 titled, ''Nitrogen Oxides (NO_X) Budget Program,'' effective January 25, 2019, which reinstates applicable portions of EPA's 40 CFR part 96 NO_X SIP Call regulations and establishes alternative emission monitoring requirements for certain units. Also, in this rule, EPA is finalizing the removal of South Carolina Regulation 61–62.96 Subparts AA through II, AAA through III, and AAAA through IIII entitled, ''Nitrogen Oxides (NO_X) and Sulfur Dioxide (SO_2) Budget Trading Program,'' from the South Carolina State Implementation Plan, which is incorporated by reference in accordance with the requirements of 1 CFR part 51. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, the these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update to the SIP compilation.[10]

III. Final Actions

EPA is approving South Carolina's SIP April 12, 2019, and July 11, 2019, SIP revisions and incorporating Regulation 61–62.96 entitled, ''Nitrogen Oxides (NO_X) Budget Program,'' and Regulation 61–62.96, Subpart H, Section 96.70 into the SIP. In addition, EPA is approving removal of the State's CAIR regulations at Regulation 61–62.96 Subparts AA through II, AAA through III, and AAAA through IIII entitled, ''Nitrogen Oxides (NO_X) and Sulfur Dioxide (SO_2) Budget Trading Program,'' from the SIP. EPA has concluded that these revisions will not interfere with attainment and maintenance of the NAAQS, reasonable further progress, or any other applicable requirement of the CAA.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 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, these actions merely approve state law as meeting Federal requirements and do not impose additional requirements beyond those imposed by state law. For that reason, these actions:

- Are not significant regulatory actions 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);
- Are not Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory actions because SIP approvals are exempted under Executive Order 12866;
- Do not impose information collection burdens under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Are certified as not having significant economic impacts on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Do not contain any unfunded mandates or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Do not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Are 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

[8] *See* ''Emissions Monitoring Provisions in State Implementation Plans Required Under the NO_X SIP Call,'' 84 FR 8422.

[9] This submission also includes amended regulations which are not part of the federally-approved SIP and are not addressed in this notice such as: Amended Regulation 61–62.61, ''South Carolina Designated Facility Plan and New Source Performance Standards;'' amended Regulation 61–62.63, ''National Emission Standards for Hazardous Air Pollutants (''NESHAP'') for Source Categories;'' amended Regulation 61–62.68, ''Chemical Accident Prevention Provisions;'' and amended Regulation 61–62.70, ''Title V Operating Permit Program.''

[10] *See* 62 FR 27968 (May 22, 1997).

• Do 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).

Because these actions merely approve state law as meeting Federal requirements and do not impose additional requirements beyond those imposed by state law, this action for the State of South Carolina does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). Therefore, this action will not impose substantial direct costs on Tribal governments or preempt Tribal law. The Catawba Indian Nation (CIN) Reservation is located within the boundary of York County, South Carolina. Pursuant to the Catawba Indian Claims Settlement Act, S.C. Code Ann. 27–16–120 (Settlement Act), ''all state and local environmental laws and regulations apply to the [Catawba Indian Nation] and Reservation and are fully enforceable by all relevant state and local agencies and authorities.'' The CIN also retains authority to impose regulations applying higher environmental standards to the Reservation than those imposed by state law or local governing bodies, in accordance with the Settlement Act.

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 September 28, 2020. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: July 13, 2020.

Mary Walker,

Regional Administrator, Region 4.

Accordingly, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart PP—South Carolina

■ 2. Section 52.2120(c) is amended by revising the entry for ''Regulation No. 62.96'' to read as follows:

§ 52.2120 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED SOUTH CAROLINA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
Regulation No. 62.96	Nitrogen Oxides (NO_X) Budget Program	1/25/2019	7/29/2020, [Insert citation of publication].	
*	*	*	*	*

* * * * *

[FR Doc. 2020–15534 Filed 7–28–20; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 85, No. 146
Wednesday, July 29, 2020

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0718; Product Identifier 2019–CE–045–AD]

RIN 2120–AA64

Airworthiness Directives; Textron Aviation Inc. Airplanes (Type Certificate Previously Held by Beechcraft Corporation)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Textron Aviation Inc. (Textron) (type certificate previously held by Beechcraft Corporation) Models F90, 65–90, 65–A90, B90, C90, H90 (T–44A), E90, 65–A90–1 (JU–21A, U–21A, RU–21A, RU–21D, U–21G, RU–21H), 65–A90–2 (RU–21B), 65–A90–3 (RU–21C), 65–A90–4 (RU–21E, RU–21H), 99, 99A, 99A (FACH), A99, A99A, B99, C99, 100, A100 (U–21F), and B100 airplanes. This proposed AD was prompted by reports of fatigue cracks in the lower forward wing fitting. This proposed AD would require a one-time inspection for the presence of washer part number (P/N) 90–380058–1 on the left-hand (LH) and right-hand (RH) lower forward wing bolt and, if applicable, removing washer P/N 90–380058–1, inspecting the wing fitting, bolt, and nut, replacing the wing fitting if it is cracked, and replacing the washer with washer P/N 90–380019–1. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 14, 2020.

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

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

For service information identified in this NPRM, contact Textron Aviation Inc., P.O. Box 7706, Wichita, KS 67277: phone: 316–517–5800; internet: *https://txtav.com/.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust St, Kansas City, MO 64106. For information on the availability of this material at the FAA, call 816–329–4148.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0718; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Brian C. Adamson, Aerospace Engineer, Wichita ACO Branch, AIR–7K3, FAA, 1801 Airport Rd, Wichita, KS 67209; phone: 316–946–4193; fax: 316–946–4107; email: *brian.adamson@faa.gov* or *Wichita-COS@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–0718; Product Identifier 2019–CE–041–AD'' at the beginning of your comments. The FAA will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Brian C. Adamson, Aerospace Engineer, Wichita ACO Branch, AIR–7K3, FAA, 1801 Airport Rd, Wichita, KS 67209; phone: 316–946–4193; fax: 316–946–4107; email: *brian.adamson@faa.gov* or *Wichita-COS@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

Textron has received reports of fatigue cracks in the lower forward wing fitting on two airplanes. Investigation revealed that installing washer P/N 90–380058–1 on the wing bolt will cause a premature torque indication. This washer may have been installed as part of kit 101–4024–3 on Models F90, 65–90, 65–A90, B90, C90, H90 (T–44A), E90, 65–A90–1 (JU–21A, U–21A, RU–21A, RU–21D, U–21G, RU–21H), 65–A90–2 (RU–21B), 65–A90–3 (RU–21C), 65–A90–4 (RU–21E, RU–21H), 99, 99A, 99A (FACH), A99, A99A, B99, C99, 100, A100 (U–21F), and B100 airplanes, or as part of kit 90–4077–1 on Models 65–90, 65–A90, 65–A90–1 (JU–21A, U–21A, RU–21A, RU–21D, U–21G, RU–21H),

65–A90–2 (RU–21B), 65–A90–3 (RU–21C), 65–A90–4 (RU–21E, RU–21H), B90, C90, and E90 airplanes. Under-torque of the wing bolt causes a reduced clamping force that changes the load path reacted by the RH and LH lower forward wing fitting.

This condition, if not addressed, could result in fatigue cracks that lead to failure of the forward lower wing fitting, wing separation, and loss of airplane control.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Beechcraft Mandatory Service Letter MTL–57–01, Revision 1, dated September 19, 2018. The service information contains procedures for a one-time inspection for the presence of washer P/N 90–380058–1 on the LH and RH lower forward wing bolt and, if applicable, removing washer P/N 90–380058–1; inspecting the wing fitting, bolt, and nut; replacing the wing fitting if it is cracked; and replacing the washer with washer P/N 90–380019–1. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

The FAA is proposing this AD because it evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of this same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously.

Differences Between This Proposed AD and the Service Information

The service information specifies inspecting within 200 flight hours or 12 months, whichever occurs earlier. This proposed AD would require inspecting within the next 200 flight hours or 12 months, whichever occurs later.

The service information applies to Models A100A and A100C airplanes, and to Model F90 with S/N LA–1. This proposed AD would not apply to these airplanes because they do not have an FAA type certificate.

This proposed AD would apply to military models T–44A, JU–21A, RU–21A, RU–21B, RU–21C, RU–21D, RU–21E, RU–21H, U–21A, U–21F, U–21G, and FACH airplanes, because these models have a civil counterpart that is subject to the unsafe condition. The service information does not apply to all of these military models.

Costs of Compliance

The FAA estimates that this proposed AD would affect 1,319 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection for washer P/N 90–380058–1 (LH Wing Fitting).	0.3 work-hour × $85 per hour = $25.50	Not applicable	$25.50	$33,634.50
Inspection for washer P/N 90–380058–1 (RH Wing Fitting).	0.3 work-hour × $85 per hour = $25.50	Not applicable	25.50	33,634.50

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
RH Wing bolt, washer, and nut removal	8 work-hours × $85 per hour = $680	$335	$1,015
LH Wing bolt, washer, and nut removal	8 work-hours × $85 per hour = $680	335	1,015
Inspection of RH Lower Forward Wing Fitting	2 work-hours × $85 per hour = $170	Not applicable	170
Inspection of LH Lower Forward Wing Fitting	2 work-hours × $85 per hour = $170	Not applicable	170
Removal and Replacement of P/N 50–120073–8 RH Lower Forward Wing Fitting.	150 work-hours × $85 per hour = $12,750	7,297.85	20,047.85
Removal and Replacement of P/N 50–120073–7 LH Lower Forward Wing Fitting.	150 work-hours × $85 per hour = $12,750	11,812.56	24,562.56

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Textron Aviation Inc. (Type Certificate previously held by Beechcraft Corporation): Docket No. FAA–2020–0718; Product Identifier 2019–CE–045–AD.

(a) Comments Due Date

The FAA must receive comments by September 14, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the Textron Aviation Inc. (type certificate previously held by Beechcraft Corporation) airplanes, certificated in any category, identified in table 1 to paragraph (c) of this AD:

TABLE 1 TO PARAGRAPH (c) OF THIS AD—APPLICABILITY

Models	Serial numbers (S/Ns)
F90	LA–2 through LA–225.
65–90, 65–A90, B90, C90.	All S/Ns.
H90 (T–44A)	LL–1 through LL–61.
E90	LW–1 through LW–347.
65–A90–1 (JU–21A, U–21A, RU–21A, RU–21D, U–21G, RU–21H).	LM–1 through LM–144.
65–A90–2 (RU–21B)	LS–1, LS–2, LS–3.
65–A90–3 (RU–21C)	LT–1 and LT–2.
65–A90–4 (RU–21E, RU–21H).	LU–1 through LU–16.
99, 99A, 99A (FACH), A99, A99A, B99, C99.	U–1 through U–239.
100, A100 (U–21F)	B–1 through B–247.
B100	BE–1 through BE–137.

(d) Subject

Joint Aircraft System Component (JASC): 5700, Wings.

(e) Unsafe Condition

This AD was prompted by information provided by Textron Aviation Inc. that a washer assembly may provide premature torque indication that could lead to cracking of the wing fitting. The FAA is issuing this AD to prevent such fatigue cracks. The unsafe condition, if not addressed, could result in failure of the forward lower wing fitting, which could lead to wing separation and loss of airplane control.

(f) Compliance

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

(g) Action

(1) Within the next 200 flight hours after the effective date of this AD or within 12 months after the effective date of this AD, whichever occurs later, inspect each washer assembly attached to the left and right lower forward wing bolts and remove all part number 90–380058–1 washers in accordance with the Accomplishment Instructions, paragraphs 3 through 5, of Beechcraft Mandatory Service Letter MTL–57–01, Revision 1, dated September 19, 2018 (MTL–57–01). In all locations where a washer part number 90–380058–1 was removed, do the following:

(i) Inspect the bolt, nut, and fitting in accordance with the Accomplishment Instructions, paragraph 6, of MTL–57–01. If there is a crack in the fitting, replace the fitting before further flight.

(ii) Install a part number 90–380019–1 washer in accordance with the Accomplishment Instructions, paragraph 7, of MTL–57–01.

(2) As of the effective date of this AD, do not install washer part number 90–380058–1 on any airplane listed in table 1 to paragraph (c) of this AD.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Wichita ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Brian C. Adamson, Aerospace Engineer, Wichita ACO Branch, AIR–7K3, FAA, 1801 Airport Rd, Wichita, KS 67209; phone: 316–946–4193; fax: 316–946–4107; email: *brian.adamson@faa.gov* or *Wichita-COS@faa.gov*. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(i) Related Information

(1) For more information about this AD, contact Brian C. Adamson, Aerospace Engineer, Wichita ACO Branch, AIR–7K3, FAA, 1801 Airport Rd, Wichita, KS 67209; phone: 316–946–4193; fax: 316–946–4107; email: *brian.adamson@faa.gov* or *Wichita-COS@faa.gov*.

(2) For service information identified in this AD, contact Textron Aviation Inc., PO Box 7706, Wichita, KS 67277: phone: 316–517–5800: internet: *https://txtav.com/*. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust St, Kansas City, MO 64106. For information on the availability of this material at the FAA, call 816–329–4148.

Issued on July 22, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–16214 Filed 7–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA–574]

RIN 1117–AB57

Reporting of Theft or Significant Loss of Controlled Substances

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend Drug Enforcement Administration (DEA) regulations regarding DEA Form 106, used by DEA registrants to report thefts or significant losses of controlled substances, to clarify that all such forms must be submitted electronically. In addition, the proposed rule would add new requirements for the form to be submitted accurately and within a 15-day time period. This proposed rule will

not change the requirement that registrants notify the DEA Field Division Office in their area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft.

DATES: Comments must be submitted electronically or postmarked on or before September 28, 2020. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

All comments concerning collection of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget (OMB) on or before September 28, 2020.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–574'' on all electronic and written correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

• *Paper comments:* Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment, *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

• *Paperwork Reduction Act Comments:* All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, 725 17th Street NW, Washington, DC 20503. Please state that your comment refers to RIN 1117–AB57/Docket No. DEA–547.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this proposed rule is available at *http://www.regulations.gov* for easy reference.

Background and Legal Authority

The Controlled Substances Act (CSA) authorizes the Administrator of DEA (by delegation from the Attorney General) to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances; maintenance and submission of records and reports; and for the efficient execution of his statutory functions. 21 U.S.C. 821, 827, 871(b). Currently, 21 CFR 1301.74(c) requires a non-practitioner registrant to notify DEA's Field Division Office in his or her area, in writing, of any theft or significant loss of any controlled substances within one business day upon discovery of such theft or loss. The provision stipulates this same notification requirement and one-day time period regarding in-transit losses of controlled substances for suppliers, importers, and exporters with certain exceptions. In addition to the requirement to notify DEA within one business day of the discovery of a theft or loss, this provision requires a non-practitioner registrant to complete and submit to the same field division office a DEA Form 106 regarding the theft or loss. This provision is silent as to the actual submission method of the DEA Form 106 (*e.g.,* mail, hand delivery, electronic) and the time period in which these reports are due. This proposed rule will not change the requirement that registrants notify the Field Division Office of the Administration in their area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft.

Similarly, 21 CFR 1301.76(b) currently requires practitioner registrants to notify DEA's Field Division Office in his area, in writing, of the theft or significant loss of any controlled substances within one business day upon discovery of the theft or loss; and to complete and submit DEA Form 106 to the same Field Division Office. Again, this provision is silent as to the actual submission method of DEA Form 106 and the due date for this report.

This proposed rule will not change the requirement under 21 CFR 1301.74(c) and 1301.76(b), respectively, that non-practitioner and practitioner registrants notify DEA's Field Division Office in their area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft.

Currently, 99.5 percent of all DEA Form 106 submissions are completed electronically via DEA's secure website. The remaining 0.5 percent of form submissions are completed by paper. See Regulatory Analyses section for additional information.

Amendments To Revise Submission Process for DEA Form 106

This proposed rule would set a 15-day calendar period for submitting a complete and accurate DEA Form 106 and clarify the form submission process, requiring all forms be submitted electronically. This would match the submission process for DEA Form 107, a form used by regulated persons [1] to report loss or disappearance of listed chemicals. As set forth in 21 CFR 1310.05(b)(1), a regulated person must file a complete and accurate DEA Form 107 with DEA through the DEA Diversion Control Diversion secure network application (available on the DEA Diversion Control Division website) within 15 calendar days after discovery of the circumstances requiring the report.

These proposed changes would make clear to registrants that all DEA Form 106 submissions must go through the secure online database, and physical copies will no longer be accepted. Through the secure online database, forms will be more easily submitted and organized.[2]

Regulatory Analyses

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

This proposed rule was developed in accordance with the principles of Executive Orders (E.O.s) 12866, 13563, and 13771. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. DEA has determined that this proposed rule is not a ''significant regulatory action'' under E.O. 12866, section 3(f).

Analysis of Benefits and Costs

DEA has examined the benefits and costs of this proposed rule. Currently, 99.5 percent of all DEA Form 106 reports are reported electronically via DEA's secure website. This proposed rule will impact the remaining 0.5 percent of responses that are reported by paper representing 181 of a total of 37,047 responses. Benefits include costs savings, as discussed in the following paragraphs, and increased simplicity in reporting theft and loss on controlled substances and clarity in the regulations. This proposed rule will add clarity to the submission method by matching the submission process and requirements for ''Reports of Loss or Disappearance of Listed Chemicals''—DEA Form 107. Additionally, electronic submissions will allow all report submissions to be received more quickly and stored in a central database, as well as allow for analysis.

There is no new cost associated with this proposed rule. The labor burden to submit DEA Form 106 is estimated to be the same for electronic and paper submissions. However, DEA anticipates there will be cost savings associated with electronic submissions. Some cost savings are described qualitatively and some are quantified. From submissions received in 2018, DEA estimates approximately 181 paper submissions per year. Many of these paper forms contain illegible or erroneous information, requiring DEA to call respondents to correct or clarify the information in the paper form, consuming both DEA's and the respondent's time and resources. Electronic submissions are expected to virtually eliminate the requirement for DEA to call back the respondent for clarifications of form data. As DEA has not tracked the number of call backs or the average duration of calls, DEA does not have a strong basis to quantify the cost savings.

This proposed rule would eliminate the need to print paper forms and transmit by mail or courier service. DEA estimates there will be a cost savings of $0.63, $0.55 for postage plus $0.08 for an envelope, or a total of $114 per year for an estimated 181 responses per year. DEA assumes the cost savings associated with not having to print is negligible.

In summary, DEA estimates the economic impact of this proposed rule is *de minimis.*

E.O. 13771 was issued on January 30, 2017, and published in the **Federal Register** on February 3, 2017.[3] Section 2(a) of E.O. 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, Section 2(c) of E.O. 13771 requires that the new incremental costs associated with new regulations, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. DEA expects this proposed rule will not be considered an E.O. 13771 regulatory action. The estimated economic impact of proposed rule is *de minimis.*

Executive Order 12988, Civil Justice Reform

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

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of E.O. 13175. This proposed rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

[1] The term ''regulated person'' is defined at 21 U.S.C. 802(38).

[2] *https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html.*

[3] 82 FR 9339.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA), DEA has reviewed the economic impact of this proposed rule on small entities. DEA's economic impact evaluation indicates that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.

The RFA requires agencies to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on a substantial number of small entities. For the purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. DEA has analyzed the economic impact of each provision of this proposed rule and estimates that the proposed rule will have minimal economic impact on affected entities, including small entities.

This proposed rule would amend regulations regarding DEA Form 106 to clarify that all submissions of the form must be submitted online. Based on actual submissions in 2018, DEA estimates there are 181 paper submissions per year, submitted by six entities: One distributor, two pharmacies, one researcher, one veterinarian service entity, and one hospital.

DEA estimates the affected entities are in the following North American Industry Classification System (NAICS) industries:

- 424210—Drugs and Druggists' Sundries Merchant Wholesalers
- 446110—Pharmacies and Drug Stores
- 541712—Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)
- 541940—Veterinary Services
- 622110—General Medical and Surgical Hospitals

The U.S. Census Bureau's Statistics of U.S. Businesses (SUSB) is an annual series that provides economic data by enterprise size and industry. SUSB data contains the number of firms for various employment or revenue size ranges for each industry. Comparing the size ranges to the U.S. Small Business Administration (SBA) size standards, DEA estimated the number of entities in each affected industry, number of small entities in each affected industry, and number of affected small entities. The table below summarizes the results.

NAICS	Description	Number of firms	SBA size standards	Number of small entities	Number of affected small entities
424210	Drugs and Druggists' Sundries Merchant Wholesalers.	6,833	250 employees	6,569	0
446110	Pharmacies and Drug Stores	18,852	$30.0 million *	18,503	0
541715	Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology).	9,864	1,000 employees	9,325	0
541940	Veterinary Services	27,708	$8.0 million *	27,564	1
622110	General Medical and Surgical Hospitals	2,904	$41.5 million *	1,199	0

* Annual revenue.

Sources: 2016 SUSB Annual Datasets by Establishment Industry, ''U.S. & states, NAICS, detailed employment sizes (U.S., 6-digit and states, NAICS sectors).'' *https://www.census.gov/data/datasets/2016/econ/susb/2016-susb.html.* (Accessed 1/14/2020.) 2012 SUSB Annual Data Tables by Establishment Industry, ''U.S., 6-digit NAICS.'' *https://www.census.gov/data/tables/2012/econ/susb/2012-susb-annual.html.* (Accessed 1/14/2020.) U.S. Small Business Administration, Table of size standards, effective Aug 19, 2019. *https://www.sba.gov/document/support--table-size-standards.* (Accessed 1/14/2020.)

There is no new cost associated with this proposed rule. The labor burden to submit DEA Form 106 is estimated to be the same for electronic and paper submissions. However, DEA anticipates there will be cost savings associated with electronic submissions. Some cost savings are described qualitatively and some are quantified. From submissions received in 2018, DEA estimates the one affected small entity submits one paper submission per year. Many of these paper forms contain illegible or erroneous information, requiring DEA to call respondents to correct or clarify the information in the paper form, consuming DEA's and the respondent's time and resources. Electronic submissions are expected to virtually eliminate the requirement for DEA to call back the respondent for clarifications of form data. As DEA has not tracked the number of call backs or the average duration of calls, DEA does not have a strong basis to quantify the cost savings.

DEA estimates there will be a cost saving associated with eliminating the need to print paper forms and transmit by mail or courier service. The estimated cost savings is $0.63, $0.55 for postage plus $0.08 for an envelope, per paper submission.

In summary, DEA estimates this rule will affect six entities who submit 181 paper DEA Forms 106. Of the affected six entities, one entity (veterinary services entity) is a small entity, submitting one paper form per year. The estimated cost savings for the affected small entity is minimal ($0.63 per year). Therefore, this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the ''Regulatory Flexibility Act'' section above, DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year * * * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), DEA has identified the following collection of information related to this proposed rule. This action would modify existing collection 1117–0001 and DEA will be submitting the revision to OMB for approval. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at *https://www.reginfo.gov/.* DEA has submitted this collection request to OMB for review and approval.

A. Collections of Information Associated With the Proposed Rule

Title: Amending Regulations Regarding DEA Form 106

OMB Control Number: 1117–0001

Form Number: DEA–106

DEA is proposing to amend its regulations for reporting thefts or significant losses of controlled substances to implement the requirement of electronic submissions for reporting the thefts or significant losses of controlled substances to clarify that all such reports must be submitted electronically within 15 days of discovery of the circumstances requiring the report. This amendment would clarify the submission process by aligning it with the current requirements of reporting losses of disappearance of listed chemicals on DEA Form 107 and no longer accepting physical copies. Form 107 (OMB Control Number 1117–0024) is also only submitted electronically, within 15 days of discovery of the circumstances requiring the report.

Currently, 99.5 percent of all DEA Form 106 reports are reported electronically via DEA's secure website. This proposed rule will impact the remaining 0.5 percent of responses that are reported by paper. Electronic submissions are expected to virtually eliminate the requirement for DEA to call back the respondent for clarifications of form data. Furthermore, this proposed rule would eliminate the need for respondents to print paper forms and transmit by mail or courier service, resulting in cost savings for the 0.5 percent of responses per year transitioning from paper to electronic forms.

The electronic submission would be filed with DEA through the DEA Diversion Control Diversion secure network application (available on the DEA Diversion Control Division website). The submissions of forms will be more easily submitted and organized through the secure database.

The DEA estimates the following number of respondents and burden associated with this collection of information:

- *Number of respondents:* 10,693.
- *Frequency of response:* 3.4646 (calculated).
- *Number of responses:* 37,047.
- *Burden per response:* 0.3333 hours.
- *Total annual hour burden:* 12,349 hours.

B. Request for Comments Regarding the Proposed Collections of Information

Written comments and suggestions from the public and affected entities concerning the proposed revision of this collection of information are encouraged. Under the PRA, DEA is required to provide a notice regarding the proposed collections of information in the **Federal Register** with the notice of proposed rulemaking and solicit public comment. Pursuant to section 3506(c)(2) of the PRA (44 U.S.C. 3506(c)(2)), DEA is soliciting comment on the following issues related to this information of collection:

- Whether the proposed collection of information is necessary for the proper performance of the functions of DEA, including whether the information will have practical utility.
- The accuracy of DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Recommendations to enhance the quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, 725 17th Street NW, Washington, DC 20503. Please state that your comments refer to RIN 1117–AB57/Docket No. DEA–574. All comments must be submitted to OMB on or before September 28, 2020. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposed rule.

If you need a copy of the proposed information collection instrument(s) with instructions or additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152–2639; Telephone: (571) 362–3261.

List of Subjects in 21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

For the reasons set out above, the DEA proposes to amend 21 CFR part 1301 as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.

■ 2. In § 1301.74, revise the fifth sentence of paragraph (c) introductory text to read as follows:

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

* * * * *

(c) * * * The registrant must also file a complete and accurate DEA Form 106 with the Administration through the DEA Diversion Control Division secure network application within 15 calendar days after discovery of the theft or loss. * * *

* * * * *

■ 3. In § 1301.76, revise the second sentence of paragraph (b) introductory text to read as follows:

§ 1301.76 Other security controls for practitioners.

* * * * *

(b) * * * The registrant must also file a complete and accurate DEA Form 106 with the Administration through the DEA Diversion Control Division secure network application within 15 calendar days after the discovery of theft or loss. * * *

* * * * *

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–15635 Filed 7–28–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[REG–111879–20]

RIN 1545–BP88

Recapture of Excess Employment Tax Credits Under the Families First Act and the CARES Act

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of Proposed Rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations pursuant to the regulatory authority granted under the Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security Act to prescribe such regulations as may be necessary for

reconciling advance payments of refundable employment tax credits provided under these acts and recapturing the benefit of the credits when necessary. These proposed regulations affect businesses and tax-exempt organizations that claim certain credits under the Families First Coronavirus Response Act for qualifying sick and family leave wages and that claim certain employee retention credits under the Coronavirus Aid, Relief, and Economic Security Act. The text of those temporary regulations serves as the text of these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by September 28, 2020. Requests for a public hearing must be submitted as prescribed in the ''Comments and Requests for a Public Hearing'' section.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–111879–20) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The IRS expects to have limited personnel available to process public comments that are submitted on paper through the mail. Until further notice, any comments submitted on paper will be considered to the extent practicable. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comment submitted electronically, and to the extent practicable on paper, to its public docket. Send paper submissions to: CC:PA:LPD:PR (REG–111879–20), room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, NaLee Park at (202) 317–6879; concerning submissions of comments and/or requests for a public hearing, Regina Johnson, (202) 317–5177 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend the Employment Taxes and Collection of Income at the Source Regulations (26 CFR part 31) relating to sections 3111 and 3221 of the Internal Revenue Code (Code) pursuant to the regulatory authority granted under the Families First Coronavirus Response Act (Families First Act) and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) to prescribe such regulations as may be necessary for reconciling advance payments of refundable employment tax credits provided under these acts and recapturing the benefit of the credits when necessary. Consistent with this authority, these proposed regulations authorize the assessment of erroneous refunds of the credits paid under sections 7001 and 7003 of the Families First Act and section 2301 of the CARES Act. The text of those temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the amendments.

Special Analyses

The Office of Management and Budget's Office of Information and Regulatory Analysis has determined that these regulations are not significant and not subject to review under section 6(b) of Executive Order 12866.

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), the Secretary certifies that these proposed regulations will not have a significant economic impact on a substantial number of small entities because these proposed regulations impose no compliance burden on any business entities, including small entities. Although these proposed regulations will apply to all employers eligible for the credits under the Families First Act and the CARES Act, including small businesses and tax-exempt organizations with fewer than 500 employees, and will therefore be likely to affect a substantial number of small entities, the economic impact will not be significant. These proposed regulations do not affect the employer's employment tax reporting or the necessary information to substantiate entitlement to the credits. Rather, these proposed regulations merely implement the statutory authority granted under sections 7001(f) and 7003(f) of the Families First Act and section 2301(l) of the CARES Act that authorize the Service to assess, reconcile, and recapture any portion of the credits erroneously paid or refunded in excess of the actual amount allowed as if such amounts were tax liabilities under sections 3111(a) and 3221(a) subject to assessment and administrative collection procedures. Notwithstanding this certification, the Treasury Department and the IRS invite comments on any impact these regulations would have on small entities.

Pursuant to section 7805(f), this notice of proposed rulemaking has been submitted to the Chief Counsel of the Office of Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are timely submitted to the IRS as prescribed in the preamble under the **ADDRESSES** section. The Treasury Department and the IRS request comments on all aspects of these proposed regulations. Any electronic comments submitted, and to the extent practicable any paper comments submitted, will be made available at *www.regulations.gov* or upon request.

A public hearing will be scheduled if requested in writing by any person who timely submits electronic or written comments. Requests for a hearing are strongly encouraged to be submitted electronically. If a public hearing is scheduled, notice of the date and time for the public hearing will be published in the **Federal Register**. Announcement 2020–4, 2020–17 IRB 1, provides that until further notice, public hearings conducted by the IRS will be held telephonically. Any telephonic hearing will be made accessible to people with disabilities.

Statement of Availability of IRS Documents

IRS notices and other guidance cited in this preamble are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *http://www.irs.gov.*

Drafting Information

The principal author of these regulations is NaLee Park, Office of the Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes). However, other personnel from the Treasury Department and the IRS participated in the development of these regulations.

List of Subjects in 26 CFR 31

Employment taxes, Income taxes, Penalties, Pensions, Railroad retirement, Reporting and recordkeeping requirements, Social security, Unemployment compensation.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 31 is proposed to be amended as follows:

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT SOURCE

■ **Paragraph 1.** The authority citation for part 31 is amended by adding entries for §§ 31.3111–6T and 31.3221–5T in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805.

* * * * *

Section 31.3111–6T also issued under sec. 7001 and sec. 7003 of the Families First Coronavirus Response Act of 2020 and sec. 2301 of the Coronavirus Aid, Relief, and Economic Security Act of 2020

* * * * *

Section 31.3221–5T also issued under sec. 7001 and sec. 7003 of the Families First Coronavirus Response Act of 2020 and sec. 2301 of the Coronavirus Aid, Relief, and Economic Security Act of 2020

* * * * *

■ **Par. 2.** Section 31.3111–6 is added to read as follows:

§ 31.3111–6 Recapture of credits under the Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security Act

[The text of proposed § 31.3111–6 is the same as the text of § 31.3111–6T published elsewhere in this issue of the **Federal Register**].

■ **Par. 3.** Section 31.3221–5 is added to read as follows:

§ 31.3221–5 Recapture of credits under the Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security Act

[The text of proposed § 31.3221–5 is the same as the text of § 31.3221–5T published elsewhere in this issue of the **Federal Register**].

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2020–16300 Filed 7–24–20; 4:15 pm]

BILLING CODE 4830–01–P

NATIONAL LABOR RELATIONS BOARD

29 CFR Part 102

RIN 3142–AA17

Representation-Case Procedures: Voter List Contact Information; Absentee Ballots for Employees on Military Leave

AGENCY: National Labor Relations Board.

ACTION: Notice of proposed rulemaking; request for comments.

SUMMARY: As part of its ongoing efforts to more effectively administer the National Labor Relations Act (the Act) and to further the purposes of the Act, the National Labor Relations Board (the Board) proposes to amend its rules and regulations to eliminate the requirement that employers must, as part of the Board's voter list requirement, provide available personal email addresses and available home and personal cellular telephone numbers of all eligible voters. The Board believes, subject to comments, that elimination of this requirement will better balance employee privacy interests against those supporting disclosure of this information. The Board also proposes an amendment providing for absentee mail ballots for employees who are on military leave. The Board believes, subject to comments, that it should seek to accommodate such voters in light of congressional policies facilitating their participation in federal elections and protecting their employment rights. The Board further believes, subject to comments, that a procedure for providing such voters with absentee ballots can be instituted without impeding the expeditious resolution of questions of representation.

DATES: Comments regarding this proposed rule must be received by the Board on or before September 28, 2020. Comments replying to comments submitted during the initial comment period must be received by the Board on or before October 13, 2020. Reply comments should be limited to replying to comments previously filed by other parties. No late comments will be accepted.

ADDRESSES: You may submit comments on this proposed rule only by the following methods:

Internet—Federal eRulemaking Portal. Electronic comments may be submitted through *http://www.regulations.gov.* Follow the instructions for submitting comments.

Delivery—Comments may be sent by mail to: Roxanne L. Rothschild, Executive Secretary, National Labor Relations Board, 1015 Half Street SE, Washington, DC 20570–0001. Because of security precautions, the Board continues to experience delays in U.S. mail delivery. You should take this into consideration when preparing to meet the deadline for submitting comments. It is not necessary to mail comments if they have been filed electronically with *regulations.gov*. If you mail comments, the Board recommends that you confirm receipt of your delivered comments by contacting (202) 273–1940 (this is not a toll-free number). Individuals with hearing impairments may call 1–866–315–6572 (TTY/TDD). Because of precautions in place due to COVID–19, the Board recommends that comments be submitted electronically or by mail rather than by hand delivery. If you feel you must hand deliver comments to the Board, hand delivery will be accepted by appointment only. Please call (202) 273–1940 to arrange for hand delivery of comments. Please note that there may be a delay in the electronic posting of hand-delivered and mail comments due to the needs for safe handling and manual scanning of the comments. The Board strongly encourages electronic filing over mail or hand delivery of comments.

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The Board will post, as soon as practicable, all comments received on *http://www.regulations.gov* without making any changes to the comments, including any personal information provided. The website *http://www.regulations.gov* is the Federal eRulemaking portal, and all comments posted there are available and accessible to the public. The Board requests that comments include full citations or internet links to any authority relied upon. The Board cautions commenters not to include personal information such as Social Security numbers, personal addresses, telephone numbers, and email addresses in their comments, as such submitted information will become viewable by the public via the *http://www.regulations.gov* website. It is the commenter's responsibility to safeguard his or her information. Comments submitted through *http://www.regulations.gov* will not include the commenter's email address unless the commenter chooses to include that

information as part of his or her comment.

FOR FURTHER INFORMATION CONTACT: Roxanne L. Rothschild, Executive Secretary, National Labor Relations Board, 1015 Half Street SE, Washington, DC 20570–0001, (202) 273–1940 (this is not a toll-free number), 1–866–315–6572 (TTY/TDD).

SUPPLEMENTARY INFORMATION: The National Labor Relations Board is proposing two amendments to its current rules and regulations governing the conduct of elections held pursuant to the Act. The first amendment would modify the Board's voter list provisions—set forth in §§ 102.62(d) and 102.67(l) of the Board's Rules and Regulations—to eliminate the requirement that the employer provide ''available personal email addresses'' and ''available home and personal cellular ('cell') telephone numbers'' of all eligible voters (including individuals permitted to vote subject to challenge) to the Regional Director and the other parties. The second amendment would modify the Board's general policy of not providing absentee ballots—not currently set forth in the rules and regulations—by establishing a procedure to provide absentee ballots to employees who would otherwise be unable to vote in the election because they are on military leave.

The Board believes, subject to comments, that the current voter list requirement affords insufficient weight to employee privacy interests, and that eliminating the required disclosure of personal email addresses and personal telephone numbers will redress this imbalance. The Board also believes, subject to comments, that it should, consistent with the policies and principles underlying other statutes, seek to maximize the opportunity for otherwise-eligible voters on military leave to participate in Board-conducted elections, and that a practical procedure providing absentee mail ballots for such voters can be implemented without impeding the expeditious resolution of questions of representation.

I. Background

The National Labor Relations Board administers the National Labor Relations Act, which, among other things, governs the formation of collective-bargaining relationships between employers and groups of employees in the private sector. Section 7 of the Act, 29 U.S.C. 157, gives employees, among other rights, the right to bargain collectively through representatives of their own choosing and to refrain from such activity.

When employees and their employer are unable to agree whether employees should be represented for purposes of collective bargaining, Section 9 of the Act, 29 U.S.C. 159, gives the Board the authority to resolve the question of representation. The Supreme Court has recognized that ''Congress has entrusted the Board with a wide degree of discretion in establishing the procedure and safeguards necessary to insure the fair and free choice of bargaining representatives by employees.'' *NLRB* v. *A. J. Tower Co.,* 329 U.S. 324, 330 (1946). ''The control of the election proceeding, and the determination of the steps necessary to conduct that election fairly were matters which Congress entrusted to the Board alone.'' *NLRB* v. *Waterman Steamship Co.,* 309 U.S. 206, 226 (1940).

Representation case procedures are set forth in the statute, in Board regulations, and in Board caselaw.[1] The Board's General Counsel has also prepared a non-binding Casehandling Manual describing representation case procedures in detail.[2] With respect to the procedures applicable to Board-conducted elections, the Act itself provides only that if the Board finds that a question of representation exists, ''it shall direct an election by secret ballot and shall certify the results thereof.'' The only express provision regarding voter eligibility in the Act pertains to employees engaged in an economic strike who are not entitled to reinstatement.[3]

Within this general framework, ''the Board must adopt policies and promulgate rules and regulations in order that employees' votes may be recorded accurately, efficiently and speedily.'' *A. J. Tower Co.,* 329 U.S. at 331. In promulgating and applying representation rules and regulations, the Board, the General Counsel and the agency's regional directors [4]—in addition to seeking efficient and prompt resolution of representation cases—have sought to guarantee fair and accurate voting, to achieve transparency and uniformity in the Board's procedures, and to update those procedures in light of technological advances. See, *e.g.,* 79 FR 74308 (Dec. 15, 2014).

A. Required Disclosure of Available Personal Email Addresses and Personal Telephone Numbers

In *Excelsior Underwear, Inc.,* 156 NLRB 1236, 1239–40 (1966), the Board established a requirement that, 7 (calendar) days after approval of an election agreement or issuance of a decision and direction of election, the employer must file an election eligibility list—containing the names and home addresses of all eligible voters—with the regional director, who in turn was to make the list available to all parties. Failure to comply with the requirement constituted grounds for setting aside the election whenever proper objections were filed. Id. at 1240. In articulating this requirement, the Board reasoned it was needed in order to ''maximize the likelihood that all the voters will be exposed to the arguments for, as well as against, union representation'' and would also ''eliminate the necessity for challenges based solely on lack of knowledge as to the voter's identity,'' thus furthering the public interest in ''the speedy resolution of questions of representation.'' Id. at 1241, 1243. The Supreme Court approved the *Excelsior* requirement in *NLRB* v. *Wyman Gordon Co.,* 394 U.S. 759, 767–768 (1969).

Aside from subsequent clarification that the list must disclose *full* names and addresses,[5] the *Excelsior* requirement stood undisturbed until 2014, when a Board majority adopted a series of amendments (the 2014 amendments) to its representation case procedures that, among other things, codified the voter list requirement.[6] In doing so, the 2014 amendments made a series of modifications to the requirement, including mandating that employers disclose ''available'' personal

[1] The Board's binding rules of representation procedure are found primarily in 29 CFR part 102, subpart D. Additional rules created by adjudication are found throughout the corpus of Board decisional law. See *NLRB* v. *Wyman-Gordon Co.,* 394 U.S. 759, 764, 770, 777, 779 (1969).

[2] NLRB Casehandling Manual (Part Two) Representation Proceedings.

[3] 29 U.S.C. 159(c)(3) (''Employees engaged in an economic strike who are not entitled to reinstatement shall be eligible to vote under such regulations as the Board shall find are consistent with the purposes and provisions of this Act in any election conducted within twelve months after the commencement of the strike.'').

[4] The Act permits the Board to delegate its decisional authority in representation cases to NLRB regional directors. See 29 U.S.C. 153(b). The Board did so in 1961. 26 FR 3811 (May 4, 1961). The General Counsel administratively oversees the regional directors. 29 U.S.C. 153(d).

[5] See *North Macon Health Care Facility,* 315 NLRB 359 (1994).

[6] These changes were made via notice-and-comment rulemaking. In the Notice of Proposed Rulemaking (NPRM) issued on February 6, 2014, a Board majority proposed numerous specific changes to its then-current rules governing the representation election process. See 79 FR 7318. The 2014 amendments were adopted via a final rule issued on December 15, 2014, which became effective on April 14, 2015. 79 FR 74308. On December 18, 2019, the Board issued a final rule that modified the 2014 amendments in various respects; that rule (the 2019 amendments) was set to take effect on April 16, 2020, see 84 FR 69524, but the effective date was postponed until May 31, 2020, see 85 FR 17500.

email addresses and home and personal cellular telephone numbers of all eligible voters.[7] Citing the twin purposes of the original *Excelsior* requirement, the 2014 amendments concluded that, in view of dramatic changes in telecommunications since 1966, disclosure of personal email addresses and telephone numbers was warranted because it would permit nonemployer parties to promptly convey information concerning the question of representation to all voters; make it more likely that nonemployer parties could respond to employee questions; allow nonemployer parties to engage with employees in a more timely manner; and facilitate faster union investigation of names included on the list, thus reducing the risk that unions would challenge voters based solely on lack of knowledge as to their identity. 79 FR 74337–74340.[8]

More specifically, the 2014 amendments justified the disclosure of personal email addresses in light of the dramatically increased role electronic communications now play in workplace communication. They also noted that, in the Board's experience, employers were making increasingly frequent use of email to communicate with employees during election campaigns. 79 FR 74336–74338.

As for personal phone numbers, the 2014 amendments acknowledged that—in contrast to email—telephonic communication existed and was already in widespread use in 1966, and also acknowledged that *Excelsior* had not required disclosure of personal telephone numbers. The 2014 amendments nevertheless concluded that personal telephone numbers should now be disclosed due to (1) the ubiquity of telephones as compared to 1966; [9] (2) the fact that voicemail and text messaging permit callers to leave messages if nobody answers the call, which was not possible in 1966; (3) the emergence of cellular and smartphones as a ''universal point of contact'' combining telephone, email, and text messaging; (4) the need to reach persons—especially low-wage workers—who rely on the telephone, rather than email, for communication; and (5) the fact that some employers may not bother to update physical addresses and may contact their employees exclusively via telephone. 79 FR 74338–74339.

The Board's initial proposal to expand the contact information required on the voter list [10] attracted voluminous comments raising concerns regarding employee privacy. The 2014 amendments acknowledged these privacy concerns, but nevertheless concluded that they were outweighed by the twin purposes underlying the disclosure requirement. 79 FR 74341–74352. More specifically, the 2014 amendments rejected comments arguing that the mere potential for misuse of the information counseled against disclosure, stated that misuse had not been a significant problem in the past, and concluded that any misuse could be dealt with if and when it occurred. 79 FR 74342–74343. The 2014 amendments also found that the limited nature of the information disclosed, the limited number of recipients, the limited purposes for which it may be used, and the supposedly limited duration of any infringement outweighed employees' acknowledged privacy interest in the information. 79 FR 74343–74344.[11] In addition, the 2014 amendments rejected claims that the disclosures would run afoul of other statutes (including FOIA, the Privacy Act, state privacy laws, the CAN–SPAM Act, and the Federal Trade Commission's Do-Not-Call Rule) and prior Board precedent. 79 FR 74344–74346, 74351–74352.[12] Finally, the 2014 amendments dismissed concerns that unwanted communications could lead to significant unwelcome costs for employees. 79 FR 74351.

Dissenting Board Members Miscimarra and Johnson criticized the 2014 amendments for failing to adequately address the privacy concerns raised by the comments, particularly the majority's failure to provide adequate protection of those concerns in the face of the expanded disclosure requirement. More specifically, the dissent contended that the 2014 amendments did not and could not provide specific appropriate restrictions on use, and remedies for misuse, of the information. Citing the prevalence of hacking, identity theft, phishing scams, and related ills, the dissent emphasized that employees who have provided personal email addresses and phone numbers to their employer may have good reasons for not wanting to share them with nonemployer parties they do not know and trust. The dissent expressed doubt that such privacy concerns would be assuaged by the majority's reliance on the ostensibly limited nature of the disclosures, observing that the disclosed information does not disappear after election day and that the limitation on use of the information (for the ''representation proceeding, Board proceedings arising from it, and related matters'') was troublingly vague and specified no remedy for violations. Finally, the dissent took issue with the majority's emphasis on the absence of abuses under the original *Excelsior* requirement, pointing out that personal email addresses and telephone numbers pose different privacy concerns from home addresses. Whereas a home is a fixed, readily identifiable point the public can visit independent of disclosure of the address, a personal email address is entirely created by the employee and is typically not identifiable at all without the employee's consent, and a personal phone number is similarly created in part by the employee, who is able to determine whether it is publicly listed and identifiable at all. The dissent accordingly asserted that employees have a greater privacy interest in

[7] The voter list requirement, as codified and modified by the 2014 amendments, is located at § 102.62(d) (for elections conducted pursuant to election agreements) and § 102.67(l) (for directed elections). In addition to requiring the disclosure of available personal email addresses and telephone numbers, the 2014 amendments modified the voter list requirement by (1) requiring the employer to furnish the work locations, shifts, and job classifications of eligible voters; (2) requiring the employer to provide the same information for individuals permitted to vote subject to challenge as required for undisputedly eligible voters; (3) requiring the employer to submit the list in an electronic format approved by the General Counsel (unless the employer certifies that it does not possess the capacity to produce the list in the required form); (4) requiring the employer to serve the list on the other parties; (5) requiring the employer to file and serve the list electronically when feasible; and (6) specifying that parties ''shall not use the list for purposes other than the representation proceeding, Board proceedings arising from it, and related matters.'' In addition, the 2014 amendments required the Employer to provide the list within 2 business days of the approval of an election agreement or direction of an election. The 2019 amendments provide that, for petitions filed on or after the effective date of those amendments (now May 31, 2020), the employer will have 5 business days to provide the list. 84 FR 69526, 69531–69532.

[8] The 2014 amendments also noted that provision of email addresses and telephone numbers would permit unions to contact employees more swiftly with respect to post-election matters that may arise. 79 FR 74340.

[9] The 2014 amendments cited statistics indicating that as of 1960, 78% of all U.S. households had a telephone, that 95% had one by 1990, and that since 2000 only about 2.4% of households have lacked a telephone. 79 FR 74338–74339.

[10] 79 FR 7326–7328, 7332, 7353–7354, 7360.

[11] The 2014 amendments also sympathized with employees who wished to reduce the annoyance and irritation of unwanted communications, but stated these concerns were outweighed by the purposes of the voter list requirement. 79 FR 74350.

[12] The 2014 amendments also rejected proposals that the Board should provide an opt-in and/or opt-out mechanism for employees who do not wish to have their personal phone numbers or email addresses disclosed, stating that the Board had rejected similar proposals in the past and that they would be burdensome for the Board and the parties, would invite new areas of litigation or otherwise lead to complicated problems and negative consequences, and could themselves invade employee privacy. 79 FR 74346–74349, 74427–74428.

personal email addresses and telephone numbers than they do in their physical addresses. 79 FR 74452–74454.

In litigation that followed the 2014 amendments, several trade and employer advocacy associations contended that the expanded disclosure requirements were unlawful, and among other arguments specifically contended that employee privacy rights ''should outweigh the desire of unions to use the latest technology to facilitate their organizing efforts.'' *Associated Builders & Contractors of Texas, Inc.* v. *NLRB,* 826 F.3d 215, 224 (5th Cir. 2016). Although the court upheld the facial validity of the required disclosure of personal email addresses and telephone numbers as a valid balancing of competing interests, see id. at 225–226,[13] the court also made clear that a different balancing of the relevant interests was permissible and even preferable, stating: ''We may favor greater privacy protections over disclosure, but . . . it is not the province of this court to inject a contrary policy preference.'' Id. at 226.

The mandatory disclosure of available personal email addresses and telephone numbers has continued to garner criticism. In *RHCG Safety Corp.,* 365 NLRB No. 88, slip op. at 9–12 (2017), Chairman Miscimarra reiterated his view that the required disclosure of personal phone numbers does not adequately accommodate employees' privacy interests in their personal phone numbers, which they may provide to a supervisor without consenting to their dissemination to third parties. On December 12, 2017, the Board issued a Request for Information that generally invited the public to respond with information about whether the 2014 amendments should be retained without change, retained with modifications, or rescinded. 82 FR 58783. Virtually every responder addressed the expanded voter list disclosures.[14] Supportive responses generally praised the provision of available personal email addresses and telephone numbers as a desirable modernization of the *Excelsior* requirement and a great help to fostering union campaign communications (and in offsetting employers' greater access to employees);[15] critical responses alleged that the 2014 amendments had not adequately considered employee privacy interests and forcefully contended that such interests should have been (or, based on subsequent developments, should now be) afforded greater weight than the 2014 amendments gave them.[16] Critical responses also reported employee complaints over the disclosures,[17] asserted that disclosures have led to harassment or excessive communications from nonemployer parties,[18] and generally contended that disclosure of contact information beyond employee names and home addresses was not necessary.[19]

B. Absentee Mail Ballots for Employees on Military Leave

As noted above, the Act contains a single provision regarding voter eligibility that pertains only to certain economic strikers, and thus neither provides for nor prohibits absentee balloting. Similarly, the Board's Rules and Regulations neither provide for nor prohibit absentee balloting. But as a general policy matter, the Board has long declined to provide absentee mail ballots. See, *e.g., NLRB* v. *Cedar Tree Press, Inc.,* 169 F.3d 794 (3d Cir. 1999) (upholding Board's absentee ballot policy). This policy is articulated in the Board's Casehandling Manual (Part Two), section 11302.4, which states that where an election is conducted manually, ''ballots for voting by mail should not be provided to, inter alia, those who are in the Armed Forces, ill at home or in a hospital, on vacation, or on leave of absence due to their own decision or condition.'' [20] Further, with specific reference to employees engaged in military service, Form NLRB–652—the template usually used for election agreements [21]—provides that ''[e]mployees who are otherwise eligible but who are in the military services of the United States may vote if they appear in person at the polls.''

The Board's general policy of not providing absentee mail ballots for employees on sick, vacation, or related types of leave on the day of election appears to have cohered relatively early in the Board's history.[22] The Board's experience with providing absentee mail ballots to employees on military leave presents a more complex picture. In December 1940, a union asked the Board to determine whether employees selected for military service would be permitted to vote by absentee ballot; the Board answered in the affirmative. *American Enka Corp.,* 28 NLRB 423, 427 (1940). Two months later, in *Cudahy Packing Co.,* 29 NLRB 830, 835–836 (1941), the Board announced that, because employees in active military

[13] See also *Chamber of Commerce of the United States of America* v. *NLRB,* 118 F. Supp. 3d 171, 213–215 (D.D.C. 2015) (rejecting challenges to expanded disclosures and specifically finding that Board had not acted arbitrarily and capriciously in expanding disclosures despite implications for employee privacy).

[14] See generally the responses to the 2017 Request for Information (available at *https://www.nlrb.gov/reports-guidance/public-notices/request-information/submissions*).

[15] See, *e.g.,* Sen. Patty Murray et al. at 4–5 (discussing how the pre-2014 voter list requirement had not been adapted to growing use of telephone and email communication); United Association of Journeymen & Apprentices of the Plumbing & Pipe Fitting Industry at 4 (praising expanded contact information disclosures in light of advances in communications technology); California Nurses Association/National Nurses United, AFL–CIO at 10 (access to phone numbers and email addresses has fostered communications among employees and ''create[d] a more equal playing field in terms of information dissemination''); Patricia M. Shea at 4 (union had better access to employees through additional voter information); Service Employees International Union, CTW, CLC at 5 (modernization of voter list helps ''ensure a more fully informed electorate, rectify the imbalance in communication inherent under the old rules, and accommodate changes in technology'').

[16] See, *e.g.,* National Grocers Association at 3–4 (urging limits on disclosure of contact information because ''[a] glance at recent headlines reveals that Americans today are increasingly concerned, with good reason, about their privacy rights'').

[17] See, *e.g.,* Associated Builders and Contractors, Inc. at 4–5 (stating that 90% of respondents to responder's internal survey ''report complaints by employees about the infringement of their privacy rights'' based on disclosure of email addresses and telephone numbers).

[18] See, *e.g.,* Independent Bakers Association at 7 (''[O]ur research found examples where labor organizations used the personal contact information provided on the Voter List to send hundreds or even thousands of unsolicited text messages, calls and emails to employees' cellphones.'').

[19] See, *e.g.,* Society for Human Rights Management and the Council on Labor Law Equality at 10 (disclosure of names and home addresses ''proved more than adequate for unions, employers, and the Board alike for nearly 50 years'').

[20] This policy also applies to mixed manual-mail ballot elections. See id. section 11335.1 (cross-referencing section 11302.4).

[21] The vast majority of Board elections are conducted pursuant to election agreements. See *https://www.nlrb.gov/news-outreach/graphs-data/petitions-and-elections/percentage-elections-conducted-pursuant-election* (91.3% of all Board elections in Fiscal Year 2019 conducted pursuant to election agreement).

[22] In an early case, the Board directed a regional director to provide absentee mail ballots for employees ''who are now on leave of absence.'' *Hirsch Shirt Corp.,* 12 NLRB 553, 567 (1939). By late 1941, however, the Board appears to have distinguished between absentee balloting by employees on military leave (which, as discussed below, was then permitted in some circumstances) and other types of absentee balloting, which were apparently not permitted. See *Bunker Hill & Sullivan Mining & Concentrating Co.,* 42 NLRB 33, 33–34 (1942). Later cases occasionally suggest a willingness to provide absentee ballots given a showing that it was necessary under the circumstances, but the Board rejected contentions that an election should be set aside because such ballots were not provided. See, *e.g., Electric Machine Controller & Manufacturing Co.,* 71 NLRB 410, 411–412 (1946); *McFarling Bros. Midstate Poultry & Egg Co.,* 123 NLRB 1384, 1391–1392 (1959). In any event, by 1966 an employer could (apparently accurately) refer to an overall Board policy of not permitting absentee balloting. See *Bray Oil Co.,* 169 NLRB 1076, 1081 (1968) (1966 letter referenced policy); *Progressive Supermarkets, Inc.,* 259 NLRB 512, 526 (1981) (employer speech referenced policy).

service or training ''will be entitled to reinstatement on their return to civilian life'' pursuant to selective service laws, they were entitled to participate in the election even if they had not worked during the payroll eligibility period.[23] Although *Cudahy Packing* did not itself expressly provide for absentee ballots for such employees, the Board subsequently provided absentee mail ballots to employees in military service. See *Truscon Steel Co.,* 36 NLRB 983, 986 (1941) (25 employees in the military service supplied with absentee ballots); see also *Wilson & Co.,* 37 NLRB 944, 951 (1941) (stating that since *Cudahy Packing,* employees in military service or training had been permitted to vote ''principally by mail ballots'').

In December 1941, however, the Board reversed course. In *Wilson & Co.,* supra, the Board held that although the reasons for extending eligibility to employees in military service or training remained valid,

> administrative experience in the ensuing months has demonstrated conclusively that it is impracticable to provide for mail balloting by this group. Administrative difficulties in determining the present location of men in military service have constantly increased with concomitant delays in arrangements for elections. The actual voting of the group by mail has seriously retarded the completion of elections in many cases, since substantial time has had to be allowed for receipt and return of mail ballots by eligibles in remote sections of the country. In addition, this form of balloting has frequently raised material and substantial issues relating to the conduct of the ballot and the election. On the other hand, actual returns from such mail ballots have been relatively small.

37 NLRB at 951–952. Stating that ''time is of the essence'' in resolving questions concerning representation, the Board determined that although it would continue to recognize the eligibility of such employees, it would discontinue the practice of absentee mail balloting and would instead only permit them to vote if they appeared in person at the polls. Id. at 952.

Following *Wilson,* the Board initially strictly adhered to both aspects of its holding regarding absentee ballots. Thus, in a series of cases the Board refused to permit absentee voting by mail,[24] even where a party claimed to have current addresses of employees in military service [25] or offered to make other accommodations to facilitate election finality.[26] As in *Wilson,* the Board emphasized the administrative difficulties of providing absentee mail ballots while also promptly resolving elections, noting that ''with individuals scattered in various units of the armed forces throughout the world, it would be virtually impossible to insure a ballot reaching each man and affording him an opportunity to return it by mail to the Regional Director unless a period of 3 months was established between the date of the Direction and the return date.'' *Mine Safety Appliances Co.,* 55 NLRB 1190, 1194 (1944). At the same time, the Board reiterated that employees in military service or training were eligible voters, and in doing so rejected stipulations that would have excluded such employees from the unit at issue. See, *e.g., Yates-American Machine Co.,* 40 NLRB 519, 522 fn. 2 (1942).[27]

Shortly after the end of the Second World War, the Board softened its stance towards absentee mail balloting by employees in military service or training. In *South West Pennsylvania Pipe Lines,* 64 NLRB 1384 (1945), the Board entertained an employer's request to provide absentee mail ballots and—after noting that no party was opposed to the use of absentee ballots ''so long as such alteration does not effect an undue delay in the final disposition''—concluded as follows:

> Under the circumstances of this case, we are of the opinion that balloting by mail of the 15 or less employees of the Company now on military leave may be accomplished so that no undue delay in determining the election will result. It is also apparent that many of the administrative complexities necessarily involved in conducting a mail ballot of absent employees—problems arising out of overlapping bargaining units, the contraction of wartime operations, conflicting reemployment rights of servicemen—are not present here. There is evidence in this record to show that ballots can be returned within 20 days. We refer, moreover, to the relatively small size of the unit involved [124 employees], the presence of adequate and accurate data (with names and addresses of servicemen) in the original record, and the fact that no substantial reconversion question is present. This is not a war plant with a rapidly diminishing work force. Certain other cases may require other action.

Id. at 1387–1388. The Board accordingly authorized the Regional Director to use absentee ballots for employees on military leave provided that one or more of the parties filed with the Regional Director ''a list containing the names, most recent addresses, and work classifications of such employees'' within 7 days of the direction of election. Id. at 1388. The Board further provided that such ballots would be opened and counted provided they were ''returned to and received at'' the regional office within 30 days ''from the date they are mailed to the employees by the Regional Director.'' Id.[28]

South West Pennsylvania Pipe Lines issued on December 13, 1945, and over the next year the Board—usually citing that case—permitted employees on military leave to vote by absentee ballot in roughly 40 cases. Despite *South West Pennsylvania Pipe Lines'* stated reliance on the relatively small size of the unit and the relatively few employees on military leave, many subsequent cases involved significantly larger units [29] and significantly larger percentages of employees on military leave permitted to vote by absentee ballot.[30] Similarly,

[23] Subject to certain exceptions, to be eligible to vote in a Board election, an employee must be employed on the eligibility date (usually the payroll period immediately preceding the date of the direction of election or approval of the election agreement) and on the date of the election. See, *e.g., Plymouth Towing Co.,* 178 NLRB 651, 651 (1969).

[24] See, *e.g., R.C. Mahon Co.,* 49 NLRB 142, 144 (1943).

[25] See, *e.g., Magnolia Petroleum Co.,* 52 NLRB 984, 988 (1943).

[26] See, *e.g., Magnetic Pigment Division of Columbia Carbon Co.,* 51 NLRB 337, 339 (1943) (refusing to provide for absentee ballots for employees in military service despite employer offer to place 14-day deadline on receipt of absentee ballots from service members stationed inside the country and to waive votes for those stationed abroad).

[27] See also *Rudolph Wurlitzer Co.,* 41 NLRB 1074, 1076 & fn. 1 (1942) (denying effect to stipulation ''insofar as it deprives persons in the armed forces of the right to vote'').

[28] In addition, the Board stated that because ''free interchange between the interested parties of information on the addresses and work categories'' of the absentee voters was necessary to avoid challenges and objections, the Board would make available to all interested parties any such information furnished to it by any other party. The Board determined that ''any information or literature bearing directly or indirectly on the election'' that parties sent to absentee voters would also need to be filed with the Board ''for inspection by or transmittal to the other parties.'' Id. at 1388 (footnote omitted).

[29] See, *e.g., Johnson-Carper Furniture Co.,* 65 NLRB 414, 416 (1946) (providing for absentee balloting by 176 employees out of unit of 393); *Mayfair Cotton Mills,* 65 NLRB 511, 512 fn. 1, 513 (1946) (providing for absentee balloting by 222 employees out of unit of 625); *Thomasville Chair Co.,* 65 NLRB 1290, 1291 fn. 2, 1292 & fn. 6 (1946) (providing for absentee balloting by over 500 employees out of unit of about 1500); *Cushman Motor Works,* 66 NLRB 1413, 1415 fn. 1, 1417 & fn. 2 (1946) (providing for absentee balloting by 140 employees out of unit of 840); *Dictaphone Corp.,* 67 NLRB 307, 308 fn. 1, 312 (1946) (providing for absentee balloting by 62 employees out of unit of 690); *Endicott Johnson Corp.,* 67 NLRB 1342, 1343 fn. 2, 1348 (1946) (providing for absentee balloting by 99 employees out of unit of 476); *Swift & Co.,* 68 NLRB 440, 445 (1946) (providing for absentee balloting by 800 employees out of unit of unspecified size).

[30] In addition to several of the cases cited immediately above, see, *e.g., U.S. Gypsum Co.,* 65 NLRB 575, 576 fn. 3, 578 (1946) (providing for absentee balloting by 65 employees out of unit of 108); *Victor Adding Machine Co.,* 65 NLRB 653, 654 (1946) (providing for absentee balloting by 24 employees out of unit of 27); *Hoosier Desk Co.,* 65 NLRB 785, 787 & fn. 4 (1946) (providing for

Continued

despite *South West Pennsylvania Pipe Lines'* emphasis on the agreement of the parties to permit absentee balloting, in several cases the Board directed absentee balloting even over a party's objection.[31] True to its suggestion that ''other cases may require other action,'' however, the Board did not simply permit absentee balloting in all cases raising the issue; in a series of cases, the Board found that the *South West Pennsylvania Pipe Lines'* conditions for permitting absentee balloting had not been met due to a lack of evidence regarding the number, names, and/or addresses of unit employees on military leave.[32]

The Board continued to permit absentee balloting pursuant to *South West Pennsylvania Pipe Lines* into early 1947,[33] but then effectively discontinued the practice. A decision from July 1947 found, citing *South West Pennsylvania Pipe Lines,* that the conditions for absentee balloting had not been met,[34] as did a decision issued in July 1949,[35] but otherwise no Board decisions from this period even mention *South West Pennsylvania Pipe Lines.* Then, in *Link Belt Co.,* 91 NLRB 1143, 1144 (1950), the Board refused to allow an employee on military leave to vote by absentee mail ballot despite the parties' agreement to permit that employee to do so. By way of explanation, the Board simply stated that ''[w]e have found . . . that mail balloting of employees on military leave is impracticable,'' and added that, ''[f]rom Board administrative experience, we conclude that it will best effectuate the policies and purposes of the Act to declare eligible to vote only those employees in the military service who appear in person at the polls.'' By way of support, the Board simply cited *Wilson* and described *South West Pennsylvania Pipe Lines* as having ''followed a different procedure in a factual situation unlike that here presented.'' [36]

Since *Link Belt, Wilson* has governed the Board's policy with respect to employees on military leave (*i.e.,* they are eligible to vote, but only if they appear at the polls), and *South West Pennsylvania Pipe Lines* has been neither discussed nor cited in any published Board decisions. Indeed, aside from reaffirming *Wilson* and *Link Belt* in 1953, no published Board decisions have engaged in any discussion of absentee balloting for military employees at all.[37]

That said, the Board, on at least one occasion, has expressed willingness to revisit its approach to absentee balloting for employees on military leave. On January 8, 1992, the Board's Division of Operations-Management issued Memorandum OM 92–2, ''Mail Ballot Elections and Absentee Mail Ballots,'' informing Regional Directors that the Board ''has decided to review the Agency's current practice and experience both with respect to mail ballot elections and with respect to the use of absentee mail ballots for employees on military leave.'' The Memorandum asked Regional Directors to provide information including the number of elections in Fiscal Years 1990 and 1991 in which absentee ballots were requested for employees on military leave, the number of cases in which objections were filed based on a refusal to supply such ballots, and the number of elections in which such requested ballots might have been determinative had they been provided, returned, opened, and counted. By internal memorandum dated March 17, 1992, the General Counsel transmitted the survey results to the Board,[38] but thereafter the Board does not appear to have taken further action with respect to reviewing (or reconsidering) its approach to absentee ballots for employees on military leave.

More recently, individual Board members have suggested that the Board should reconsider its policy in this area. In *U.S. Foods, Inc.,* Case No. 15–RC–076271 (May 23, 2012) (not reported in Board volumes), Member Hayes stated his view that ''at some point . . . the Board should reconsider its general policy of not providing mail ballots to employees who are unable to participate in a manual ballot election because they are in the military service.'' And in *Tri-County Refuse Services, Inc. d/b/a Republic Services of Pinconning,* Case No. 07–RC–122650 (Sep. 9, 2014) (not reported in Board volumes), a case in which the Board overruled an employer's objection contending that the voting period should have been extended to accommodate an employee who was out of state on military leave on the election date, Member Johnson agreed that the objection should be overruled, but also found merit

> in the Employer's argument that Board policies in this area may run afoul of the spirit, if not the letter, of the Uniformed Services Employment and Reemployment Rights Act (USERRA), 38 U.S.C. 4301–4355 (1994), and other laws and public policies designed to protect the rights of service members to vote. Moreover, the Board should remove any impediment to military service in interpreting election rules under the Act. As a result, he believes the Board in the future should provide military ballots to employees who are unable to participate in manual ballot elections as a result of military service obligations that call them away from the workplace.

Although the Board majority in both *U.S. Foods* and *Tri-County Refuse* did not similarly state an interest in

absentee balloting by 48 employees out of unit of 109); *Raleigh Coca Cola Bottling Works,* 65 NLRB 1010, 1012–1013 (1946) (providing for absentee balloting by 38 employees out of unit of 70); *Welch Furniture Co.,* 65 NLRB 1197, 1198 fn. 1, 1199 & fn. 4 (1946) (providing for absentee balloting by 46 employees out of unit of 99); *Thompson Products, Inc.,* 66 NLRB 123, 124 fn. 2, 125–126 (1946) (providing for absentee balloting by 115 employees out of unit of 171); *U.S. Gypsum Co.,* 66 NLRB 619, 623–624 (1946) (providing for absentee balloting by 150 employees out of unit of 270).

[31] See, *e.g., Keystone Steel & Wire Co.,* 65 NLRB 274, 280 (1946); *U.S. Gypsum Co.,* 65 NLRB 1427, 1429 (1946); *Rockford Metal Products Co.,* 66 NLRB 538, 543 (1946); *Marsh Furniture Co.,* 66 NLRB 133, 136 & fn. 6 (1946).

[32] See, *e.g., Tennessee Coal, Iron & Railroad Co.,* 65 NLRB 1416, 1418 (1946) (declining to permit absentee balloting due to inadequate evidence regarding the number, names, and addresses of employees in the unit on military leave and insufficient evidence ''as to the availability of such information''); *Joseph Bancroft & Sons Co.,* 67 NLRB 678, 681 (1946) (declining to provide for absentee balloting given employer's admission that it did not have, and would not be able to obtain, addresses of employees in the armed forces); *Swift & Co.,* 71 NLRB 727, 729 (1946) (declining to permit absentee balloting where employer had addresses for only 247 of 566 employees still on military leave, and correctness of addresses for those 247 employees was doubtful). See also *Scripto Manufacturing Co.,* 67 NLRB 1078, 1080 (1946) (overruling objection alleging that run-off election should have provided for absentee balloting by employees in the armed forces because issue had not been raised at pre-election hearing and there was no showing that mail ballot was ''feasible'' under the particular circumstances of that case).

[33] See *Kennametal, Inc.,* 72 NLRB 837 (1947).

[34] See *Iowa Packing Co.,* 74 NLRB 434, 437 (1947) (employer only had correct addresses for 12 of 404 employees in military service who had not yet applied for reemployment).

[35] See *Frank Ix & Sons Pennsylvania Corp.,* 85 NLRB 492, 493 (1949) (although parties agreed to permit absentee balloting for 10 employees, Board did not provide for it due to lack of information regarding addresses and employer's mere contention that ''we think . . . we can obtain their whereabouts at the time the ballots would be mailed to them'').

[36] A subsequent Board decision indicates that the Board's decision in *Link Belt* followed ''an extensive survey conducted among the Board's Regional Directors,'' but does not elaborate on the results of this survey. *Atlantic Refining Co.,* 106 NLRB 1268, 1275 (1953).

[37] In *Pepsi Cola Bottling Co. of Princeton, Inc.,* 176 NLRB 716, 726, 729 (1969), a trial examiner sustained an objection alleging that because the employer was aware, two weeks before the election, that 3 employees would be absent due to National Guard duty on the day of the election, and because the employer had made no effort to secure absentee ballots for them, the employer had improperly prevented these employees from voting. The Board did not pass on this finding, however. See id. at 716 fn. 1.

[38] The results revealed 6 cases each in Fiscal Years 1990 and 1991 in which absentee ballots for employees on military leave had been requested, with no objections filed based on the refusal to provide them and no elections in which such ballots might have been determinative had they been provided, returned, opened, and counted.

reconsidering the Board's absentee ballot policy, in both cases the Board seemingly signaled a willingness to permit absentee ballots for employees on military leave under at least some circumstances. Thus, in *U.S. Foods,* the Board, in the context of a mixed manual-mail ballot election, directed the Regional Director to provide a mail ballot to an employee based at the manual balloting location who was abroad on military leave.[39] And in *Tri-County Refuse,* the Board suggested that parties could enter into stipulated election agreements providing for absentee ballots for employees on military leave.

II. Statutory Authority and Desirability of Rulemaking

Section 6 of the Act, 29 U.S.C. 156, provides that ''[t]he Board shall have authority from time to time to make, amend, and rescind, in the manner prescribed by subchapter II of chapter 5 of Title 5 [the Administrative Procedure Act], such rules and regulations as may be necessary to carry out the provisions of this Act.'' The Board interprets Section 6 as authorizing the proposed rules and invites comments on these issues. Although the Board historically has made most substantive policy determinations through case adjudication, the Board has, with Supreme Court approval, engaged in substantive rulemaking. *American Hospital Assn.* v. *NLRB,* 499 U.S. 606 (1991) (upholding Board's rulemaking on appropriate bargaining units in the healthcare industry); see also *NLRB* v. *Bell Aerospace Co.,* 416 U.S. 267, 294 (1974) (''[T]he choice between rulemaking and adjudication lies in the first instance within the Board's discretion.'').

The Board finds that informal notice-and-comment rulemaking with respect to the policies at issue here is desirable for several important reasons. First, rulemaking presents the opportunity to solicit broad public comment on, and to address in a single proceeding, two related issues that would not necessarily arise in the adjudication of a single case. By engaging in rulemaking after receiving public comment on the issues presented, the Board will be better able to make informed judgments as to (1) whether the current voter list disclosures sufficiently account for employee privacy concerns, and (2) whether it should provide absentee ballots for employees on military leave. Second, the proposed amendments will be rules of general application in representation cases, and thus the types of rules for which the Act's rulemaking provisions ''were designed to assure fairness and mature consideration.'' *Wyman-Gordon Co.,* 394 U.S. at 764. Third, the proposed amendment to the voter list requirement would affect all parties to virtually all Board-conducted elections, and the proposed amendment permitting absentee ballots for employees on military leave would additionally affect individual voters in many Board-conducted elections. Notice-and-comment rulemaking will accordingly ''provide the Board with a forum for soliciting the informed views of those affected in industry and labor before embarking on a new course.'' *Bell Aerospace,* 416 U.S. at 295. Fourth, by establishing the new policies with respect to voter lists and absentee ballots for employees on military leave in the Board's Rules & Regulations, the Board will enable employers, unions, and employees to plan their affairs free of the uncertainty that the legal regime may change on a moment's notice (and possibly retroactively) through the adjudication process. See *Wyman-Gordon,* 394 U.S. at 777 (''The rule-making procedure performs important functions. It gives notice to an entire segment of society of those controls or regimentation that is forthcoming.'') (Douglas, J., dissenting). Finally, with respect to the proposed amendment providing absentee ballots for employees on military leave, the Board wishes to facilitate maximum participation by the Board's stakeholders, the general public, and other government agencies in order to ensure that, if adopted, the proposed amendment is accompanied by procedures that also continue to effectuate the Board's commitment to the expeditious resolution of questions of representation.

III. The Proposed Rule Amendments

A. Elimination of Provision of Personal Email Addresses and Telephone Numbers in Voter List

The Board is inclined to believe, subject to comments, that the required provision of available personal email addresses and home and cellular telephone numbers should be eliminated in light of technological developments since 2014 and ongoing privacy concerns.[40]

The 2014 amendments in effect concluded that disclosure of this contact information was required because, due to changes in communications technology since 1966, supplying nonemployer parties with such information would better serve the twin purposes underlying the original *Excelsior* requirement (*i.e.,* facilitating a more informed electorate and expeditiously resolving questions of representation by avoiding challenges). The 2014 amendments acknowledged that these same changes in technology have also raised concerns regarding privacy, but ultimately concluded that the admitted interest in privacy was outweighed by the importance of expanding unions' access to voters. 79 FR 74315, 74341–74343.

The Board acknowledges that the *Excelsior* Board did not necessarily intend to limit the *Excelsior* requirement to full names and physical addresses alone for all time, and that it accordingly was appropriate for the 2014 amendments to consider whether changes in telecommunications that have taken place since 1966 warranted additional disclosures. The Board also agrees that privacy interests must be weighed against the potential benefits of disclosure, and it defers to the judgment of the courts that the 2014 amendments reached a permissible result in requiring the disclosure of personal telephone numbers despite privacy concerns.[41] Nevertheless, upon reflection the Board is inclined, as a policy matter, to conclude that privacy interests and their protection should be entitled to greater weight than the 2014 amendments accorded them, and that when given proper weight the privacy interests at stake outweigh the interests favoring mandatory disclosure of available personal email addresses and telephone numbers.

To begin, the Board is inclined to believe that the 2014 amendments overemphasized the degree to which disclosure of personal email addresses and telephone numbers advanced the twin purposes of the *Excelsior* requirement. Although the supplementary information to the 2014 amendments repeatedly stated that disclosure would advance these purposes, it identified no tangible

[39] The Board specified, however, that the employee on military leave was being provided with a mail ballot ''consistent with the election arrangements pertaining to mail ballots,'' that ballots were to be counted on time, and that the employee's ballot was ''subject to the same challenges as any other ballot.'' Even with these caveats, the Board's provision of the ballot in *U.S. Foods* appears to be in at least some tension with the nonbinding Casehandling Manual (Part Two), which states, even in the context of mixed manual-mail ballot elections, that absentee ballots are not provided in Board elections. See section 11335.1 (citing section 11302.4).

[40] The Board is not proposing any further changes to the voter list requirement as codified and modified by the 2014 amendments.

[41] *See Associated Builders and Contractors of Texas, Inc.* v. *NLRB,* 826 F.3d at 224–226; *Chamber of Commerce of the United States of America* v. *NLRB,* 118 F. Supp. 3d at 171, 212–215.

evidence that unions were previously unable to contact eligible voters in a timely fashion when limited to physical addresses, nor did it establish that challenges based on a union's lack of knowledge of a voter's identity were responsible for undue delays in resolving questions of representation. This is not to suggest that disclosure of personal telephone numbers and email addresses did not or could never advance the purposes of the *Excelsior* requirement; it is only to state that the Board is inclined to believe that those purposes were already being sufficiently served prior to the 2014 amendments.

Turning to the countervailing privacy interests, the Board is of the view that the 2014 amendments imprecisely identified the privacy interest at stake. To be sure, one dimension of the privacy interest in telephone numbers and email addresses—or, indeed, any type of contact information—is the right of the individual to be left alone. In upholding the *Excelsior* rule, the Supreme Court recognized that it is for the Board to weigh the interest in the fair and free choice of bargaining representatives against ''the asserted interest of employees in avoiding the problems that union solicitation may present.'' *Wyman-Gordon,* 394 U.S. at 767. Generally speaking, the ''problems of union solicitation'' can be described as infringements of or intrusions into the employees' personal spheres. *See, e.g.,* 79 FR 74344. If, however, the privacy interest is defined solely in these terms, then under the rationale of *Excelsior* the interest in being left alone should *always* be outweighed by the interests served by disclosing contact information because any such disclosure ''remove[s an] impediment to communication,'' and the ''mere possibility that a union will abuse the opportunity to communicate with employees'' does not, by itself, outweigh the removal of the impediment. *Excelsior,* 156 NLRB at 1240, 1244.

But the Board is inclined to find that the privacy interest at stake is not solely limited to the interest in being left alone. As the 2014 amendments recognized, the privacy interest is also implicated by the fact of disclosure itself because ''some employees will consider disclosure of the additional contact information * * * to invade their privacy, even if they are never contacted.'' 79 FR 74343. Put differently, an individual has a privacy interest ''in controlling the dissemination of information regarding personal matters.'' *U.S. Dept. of Defense* v. *FLRA,* 510 U.S. 478, 500 (1994).[42] Despite recognizing this aspect of the privacy interest at stake, the 2014 amendments do not appear to have fully appreciated it. In this regard, almost immediately after acknowledging that disclosure itself implicates privacy interests, the 2014 amendments reverted to explaining how ''many features of the voter list amendments help to minimize any invasion of employee privacy *caused by* disclosure of the information.'' 79 FR 74343 (emphasis added). Specifically, the 2014 amendments emphasized that the information disclosed is limited in scope, available only to a limited group of recipients, and can be used only for limited purposes, and that any infringement it occasions will likely be of relatively limited duration. 79 FR 74343–74344.[43] All well and good, but if disclosure itself implicates privacy concerns, limitations on what can be done with the information after disclosure are beside the point.[44]

Mindful that the fact of disclosure itself, not just undesired contact that may follow from it, is part of the privacy interest at stake here, the Board is inclined to find that the privacy interest in nondisclosure of personal telephone numbers and email addresses is entitled to substantially greater weight than it was given by the 2014 amendments. First, concerns about the protection of privacy interests have grown exponentially in conjunction with the accompanying rapid development of communications technology and the novel problems that have come with it. Just as the Board in 1966 could not possibly have imagined the proliferation of mobile smartphones, the Board could not have envisioned the rampancy of data and identity theft in today's information- and data-based society. Personal telephone numbers present special concerns in this regard: As explained in a recent *Wired* article, ''phone numbers have become more than just a way to contact someone,'' but have increasingly been used by companies and services as a means for both identification and verification of identity, thereby turning phone numbers into ''a skeleton key into your entire online life.'' [45] The news is rife with stories of large-scale data theft as well as thefts of individual phone numbers and the mischief that can result, such as ''SIM swap'' attacks in which hackers convince a target's phone company to direct the target's text messages to a different SIM card, thereby intercepting two-factor authentication login codes enabling hackers to infiltrate the target's accounts.[46] Personal email addresses present similar concerns, as they are the principal point of attack for ever-expanding forms of email fraud (such as spoofing, phishing, and other forms of social engineering), scams, and hacking.[47] This is not to suggest that unions would be tempted to engage in such behavior upon receiving employee telephone numbers or email addresses, but rather to illustrate that there is a heightened privacy interest with respect to controlling the disclosure itself.

Second, the lack of an opt-out procedure entitles the privacy interest in personal telephone numbers and email addresses to greater weight. For the purposes of this proceeding, the Board assumes that the 2014 amendments were correct that crafting an opt-out provision would be difficult

[42] *U.S. Dept. of Defense* v. *FLRA* involved the interaction of FOIA and the Privacy Act. The Board does not suggest that this case mandates eliminating the mandatory disclosure of available personal telephone numbers and email addresses, but it is clearly instructive regarding the nature of employee privacy interests in employees' personal contact information.

[43] The 2014 amendments also suggested that employees have some measure of control over whether their email addresses and telephone numbers are disclosed based on the fact that the employees have already disclosed such information to the employer. 79 FR 74343 n.169. The Board is not inclined to agree with this assessment. Employers may require provision of personal contact information as a condition of hire or continued employment (in which case the employees' ''control'' is limited to a choice between working or not working), and in any event the Board thinks it is misguided to suggest that employees should somehow anticipate in advance that their contact information might be disclosed to a third party at some future point.

[44] Several submissions in response to the 2017 Request for Information anecdotally illustrate that disclosure itself implicates the privacy interest at stake here. In this regard, several commenters, including employer groups, reported that since the 2014 amendments have taken effect, employees have lodged complaints with their employers upon discovering that their contact information had been disclosed to a union pursuant to the voter list requirement.

[45] Lily Hay Newman, ''Phone Numbers Were Never Meant as ID. Now We're All At Risk,'' *Wired* (Aug. 25, 2018), *https://www.wired.com/story/phone-numbers-indentification-authentication/?verso=true.*

[46] Andy Greenberg, ''So Hey You Should Stop Using Texts For Two-Factor Authentication,'' *Wired* (June 26, 2016), *https://www.wired.com/2016/06/hey-stop-using-texts-two-factor-authentication/.*

[47] *See, e.g.,* Federal Bureau of Investigation Alert Number I–071218–PSA (Jul. 12, 2018), available at *https://www.ic3.gov/media/2018/180712.aspx* (detailing growth of Business Email Compromise/Email Account Compromise scam). See generally Federal Bureau of Investigation internet Crime Complaint Center, ''2018 internet Crime Report,'' available at *https://pdf.ic3.gov/2018_IC3Report.pdf* (detailing internet crimes, including email fraud, in 2018); Federal Bureau of Investigation internet Crime Complaint Center Press Room, available at *https://www.ic3.gov/media/default.aspx* (containing press releases describing various email and internet-related scams).

and impractical and would also be of limited utility given the relatively short period of time during which contacts would occur between the union and the employees. See 79 FR 74348–74349. The lack of a practical opt-out mechanism raises immediate concerns with respect to telephone numbers, given that telephone calls and text messages are subject to the user's talk, text, and/or data plan. Although many such plans are unlimited, many are not or are ''pay-as-you-go'' plans. A user may still be able to avoid depleting any minutes limit or incurring additional charges by declining an incoming phone call, but users typically will not be in a position to avoid unsolicited text messages in advance of receiving one from a particular sender, and although they may be able to block such messages thereafter, the text has already been counted towards the plan limit and/or charges may have been incurred. The 2014 amendments responded to this risk by predicting it was unlikely that a union would place so many calls or send so many texts as to financially harm recipients without unlimited calling and text plans, reiterating that the use of telephone numbers would be restricted to the representation and related proceedings, and referring to the Federal Communications Commission's initiatives to address ''bill shock.'' 79 FR 74351. All of this misses the point, however, because for individuals with limited plans a single answered telephone call or a single unsolicited text message counts toward their plan limit at best or exceeds that limit and results in additional charges at worst. This concern is also present for email addresses, as email is increasingly accessed from smartphones,[48] and accessing email via such devices also counts toward a user's data limits. Here, too, the point is not that the disclosure can lead, or has led, to larger bills for employees; it is that employees have a stronger privacy interest in their telephone numbers and email addresses for this reason.

Third, the Board is inclined to agree with the view, expressed by dissenting Members Miscimarra and Johnson in 2014, that employees have a greater privacy interest in personal phone numbers and email addresses than they do in home addresses. As the dissenting members stated, a home is a fixed point that can be visited independent of disclosure of the address, whereas a personal email address is entirely the creation of the employee and typically is not identifiable at all without the employee's consent. A personal phone number is also created in part by the employee, who can determine whether it is publicly listed. Further, the Board is inclined to find that the emergence of smartphones as a ''universal point of contact,'' as well as the general proliferation of cellular telephones, also heightens the privacy interest in telephone numbers. As cellular telephone ownership has increased, and as more households have abandoned landlines,[49] specific phone numbers have become increasingly associated with particular individuals and their particular mobile device of choice, and this association can persist despite relocations that, in another era, would have required changing telephone numbers. Thus, although the ubiquity and convenience of cellular telephones means that disclosure of telephone numbers could serve the *Excelsior* purposes, the close association of telephone numbers with particular individuals also increases the privacy interest that those individuals have in their personal telephone numbers.

Taking these considerations together, the Board believes, subject to comments, that employees clearly have a heightened privacy interest in their personal email addresses and telephone numbers.[50] The Board is also inclined to find that this heightened privacy interest outweighs the competing interest in disclosure not only for the reasons listed above, but also because (1) unions will continue to have adequate alternative means of reaching employees, just as they did before the 2014 amendments; (2) unions will continue to be able to avail themselves of the other expanded disclosures required by the 2014 amendments, which the Board does not propose eliminating; and (3) unions will, of course, continue to be able to avail themselves of the traditional tools and techniques they have at their disposal to encourage employees to voluntarily disclose other contact information.

In sum, the Board is inclined to find that eliminating the mandatory disclosure of employees' personal telephone numbers and email addresses strikes a better balance between the purposes underlying the voter list requirement and employee privacy concerns.

B. Provision of Absentee Ballots to Individuals on Military Leave

The Board is inclined, subject to comments, to adopt a procedure that will provide absentee mail ballots for employees on military leave.[51] This proposal represents a limited exception to the Board's general policy of not providing absentee ballots; the Board is not inclined to modify that policy in any further respects.[52]

To begin, the Board has, from its earliest days, zealously protected the eligibility of employees on military leave. From *Cudahy* forward, the Board has held that such employees are eligible voters, even if they would not otherwise meet the Board's eligibility criteria, and the Board has refused to honor stipulations that would have excluded such employees from the

[48] As of February 2019, approximately 81% of U.S. adults owned a smartphone. Pew Research Center internet & Technology, Mobile Fact Sheet (Jun. 12, 2019), available at *https://www.pewresearch.org/internet/fact-sheet/mobile/.*

[49] As of the second half of 2018, 57.1% of all households did not have a landline telephone but did have at least one wireless telephone, and approximately 56.7% of all adults in the U.S. lived in wireless telephone-only households. Stephen J. Blumberg and Julian V. Luke, ''Wireless Substitution: Early Release of Estimates From the National Health Interview Survey, July-December 2018,'' National Center for Health Statistics (Jun. 2019), *https://www.cdc.gov/nchs/data/nhis/earlyrelease/wireless201906.pdf.*

[50] The Board is also inclined, subject to comments, to find that there is no meaningful distinction between personal email addresses and telephone numbers with respect to the privacy interests at stake. Although there may be minor distinctions between the two, the considerations identified above apply to both types of contact information. In addition, the 2014 amendments do not appear to have suggested any meaningful difference in the privacy interests involved, nor did the courts who considered challenges to the 2014 amendments suggest there is any such difference. See *Associated Builders and Contractors of Texas* v. *NLRB,* 826 F.3d at 225–226; *Associated Builders and Contractors of Texas* v. *NLRB,* 2015 WL 3609116 at *9–11 (W.D. Tex. June 1, 2015); *Chamber of Commerce* v. *NLRB,* 118 F. Supp. 3d at 213.

[51] The Board is currently subject to a budgetary rider that prohibits it from using any appropriated funds ''to issue any new administrative directive or regulation that would provide employees any means of voting through any electronic means in an election to determine a representative for the purposes of collective bargaining.'' *See, e.g.,* ''Justification of Performance Budget for Committee on Appropriations, Fiscal Year 2020'' at 5, available at *https://www.nlrb.gov/sites/default/files/attachments/basic-page/node-1706/performance_justification_2020.pdf.* Accordingly, at this time any absentee balloting must be accomplished by mail ballot.

[52] On this count, the Board is inclined to find that military leave presents distinct concerns and considerations from other types of leave. As previously indicated, although the Board has changed course at least three times with respect to absentee balloting by employees on military leave, the Board has much more consistently rejected arguments that absentee ballots should have been provided to employees on other types of leave. The Board is inclined to believe this distinction is justified due to the fact that other types of leave are more readily within an employee's control (*e.g.,* vacation) or frequently cannot be anticipated ahead of time (*e.g.,* sick leave). And as a general matter, for employees on other types of leave, the Board is inclined to agree with the Third Circuit's enumeration of the policy reasons for not permitting absentee ballots. *See Cedar Tree,* 169 F.3d at 797–798.

bargaining unit. Although the *Wilson* Board may have had valid reasons for declaring absentee ballots for military personnel ''impracticable,'' the Board's subsequent experience under *South West Pennsylvania Pipe Lines* demonstrates that absentee balloting was nevertheless feasible, even in situations involving large units and large percentages of employees on military leave voting by absentee ballot. The *Link Belt* Board's reversion to declaring such balloting ''impracticable'' was ill-explained, as was its purported distinction of *South West Pennsylvania Pipe Lines.* The Board is accordingly inclined to find, subject to comments, that it should not continue deferring to the judgment expressed in *Wilson* and *Link Belt.*

In addition, the Board is also inclined to find, subject to comments, that the types of administrative difficulties cited in *Wilson* and *Link Belt* are less pronounced, and/or more easily dealt with, due to advances in transportation and telecommunications that have occurred since 1950. At present, first-class domestic mail is delivered within 1 to 3 business days.[53] And even for those service members stationed abroad, it appears that letters sent via priority mail can usually be delivered within two weeks.[54] Based on these estimates, the Board is inclined to find that there is no longer any basis to conclude, as the Board did under *Wilson,* that 3 months from the Direction of Election to the return date would be required to accommodate absentee balloting by employees on military leave. See *Mine Safety Appliances,* 55 NLRB at 1194.

Further, telecommunications have evolved markedly since 1950, as a result of which the Board anticipates it will be much easier to determine the locations and addresses of any employees on military leave. The Board is inclined to believe that most employees on military leave will have provided their employer with their contact information, and so determining such employees' mailing addresses may often be as simple as sending an employee an email to ask for it. Even where this is not possible, the Board is inclined to believe that employers will possess sufficient information to permit the parties to use the military personnel locator services provided by the U.S. Navy,[55] U.S. Marine Corps,[56] U.S. Army,[57] and U.S. Air Force.[58] Moreover, so long as an employee's installation is known, the Department of Defense website provides a convenient tool for obtaining the installation's mailing address.[59] And in at least some instances, the Board anticipates that employees on certain types of military leave will be reachable at their home address, which the employer is already required to provide to the Board pursuant to the voter list requirement discussed at greater length above. Based on these considerations, the Board is inclined to conclude, subject to comments, that the difficulties in locating and securing mailing addresses for employees on military leave are far less likely to be present today than was the case when *Wilson* and *Link Belt* were decided.

Perhaps more importantly, the Board is inclined to agree with former Member Johnson's suggestion that provision of absentee mail ballots to individuals on military leave would be more consistent with other laws and public policies than the Board's current refusal to provide absentee ballots. In this regard, the Board is inclined, subject to comments, to conclude that Congress has manifested an approach or general policy of providing special protections to service members, especially with respect to matters of employment and voting. In 1940, before *Cudahy,* Congress enacted the Soldiers' and Sailors' Civil Relief Act—which in 2003 was restated, clarified, revised, and retitled the Servicemembers Civil Relief Act[60]—which provides a wide range of protections for servicemembers as they enter active duty.[61] *Cudahy*'s holding was itself based on a congressional statute and resolution entitling servicemembers to reinstatement of their pre-service employment.[62] More recently, in the Uniformed Services Employment and Reemployment Rights Act of 1994 (USERRA),[63] Congress similarly provided a range of employment protections for servicemembers in order to, among other things, encourage military service ''by eliminating or minimizing the disadvantages to civilian careers and employment which can result from such service.'' 38 U.S.C. 4301(a)(1).[64] In addition, in 1986 Congress passed the Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA),[65] which provides various protections and mechanisms for absentee voting in federal elections by military personnel and overseas citizens. UOCAVA has been amended several times in order to facilitate its purposes; of particular note here, amendments made as part of the National Defense Authorization Act for Fiscal Year 2002 stated that it is the sense of Congress that all administrators of Federal, State, or local elections ''should be aware of the importance of the ability of each uniformed services voter to exercise the right to vote'' and should perform their duties to ensure that uniformed services voters receive ''the utmost consideration and cooperation when voting'' and that ''each valid ballot cast by such a voter is duly counted.'' [66]

The Board does not suggest that any of these statutes apply to Board-conducted elections or require the provision of absentee ballots to employees on military leave. But taken together, they do indicate a national policy that favors taking measures to ensure that servicemembers' employment and electoral rights are preserved. Indeed, this policy has informed the Act itself: Section 10(b) (as amended in 1947), 29 U.S.C. 160(b), provides that no complaint shall issue based on any unfair labor practice occurring more than six months prior to the filing of the charge ''unless the person aggrieved thereby was prevented from filing such charge by reason of service in the armed forces in which event the six-month period shall be computed'' from the date of discharge. Given that the Act itself reflects this policy, that Board-conducted elections implicate the employment-related rights of those on military leave, and that Congress has exhorted administrators who conduct political elections to facilitate the right of servicemembers to vote, the Board is inclined to find, subject to comments, that it too should provide for absentee balloting by employees on military leave.

The Board recognizes that adopting a policy of providing for absentee mail ballots presents a number of logistical challenges. The Board believes,

[53] *See https://www.usps.com/ship/first-class-mail.htm.*

[54] According to the United States Post Office, the normal mail transit times for Priority Mail Letters via Military APO/FPO/DPO Mail are as follows: 7–9 days for locations in Germany, 11–13 days for locations in Iraq/Kuwait/Afghanistan, 8–10 days for locations in Japan/Korea, and 15–18 days for locations in Africa. *https://faq.usps.com/s/article/How-long-will-it-take-for-mail-to-reach-a-MPO.*

[55] *https://www.navy.mil/navydata/nav_legacy.asp?id=168.*

[56] *https://www.marines.mil/FAQ/.*

[57] *Id.*

[58] *https://www.afpc.af.mil/Support/Worldwide-Locator/.*

[59] *See https://installations.militaryonesource.mil/.*

[60] *See* Public Law 108–189, Dec. 19, 2003, 117 Stat 2935.

[61] *See* 50 U.S.C. 3910 *et seq.*

[62] *See* 29 NLRB at 835 fn. 5.

[63] *See* 38 U.S.C. 4301 *et seq.*

[64] Congress also stated that the Federal Government should be a model employer in carrying out the provisions of USERRA. 38 U.S.C. 4301(b).

[65] 52 U.S.C. 20301 *et seq.* (as amended).

[66] Public Law 107–107, div. A, title XVI, Sec. 1601(a)(1), (2)(A)–(B), Dec. 28, 2001, 115 Stat. 1012.

however, that these can be avoided if the absentee ballot procedure is properly structured. The Board is accordingly soliciting comments from stakeholders, the general public, the Board's regional personnel, and other governmental agencies regarding what procedures should apply if the Board adopts the proposed amendment. Among other things, commenters are invited to address:

- Whether there should be a time limit on when an absentee ballot may be requested;
- who should be permitted and/or required to request absentee ballots on behalf of employees on military leave;
- whether the Board should require documentary proof that the individual will in fact be on military leave at the time of the election;
- how the Board should approach securing the addresses of employees on military leave, including whether the parties should be responsible for doing so;
- whether time limits on returning absentee ballots should be set and, if so, what those time limits should be;
- whether other procedures or provisions are necessary or desirable to help avoid challenges to or objections over absentee ballots.

Subject to any such comments that may be received, the Board's preliminary inclination is to adopt a new procedure, rather than reinstate the standard applied under *South West Pennsylvania Pipe Lines.* That procedure involved case-specific determinations as to whether absentee ballots were warranted, and the Board suspects that such individualized determinations were part of the reason the *Link Belt* Board opted to return to *Wilson's* blanket prohibition on absentee ballots. Further, despite *South West Pennsylvania Pipe Lines'* guidance regarding these determinations, the application of that guidance in subsequent cases is often difficult to understand and not always consistent with *South West Pennsylvania Pipe Lines* itself.[67] Nor is the Board inclined to engage in individualized determinations as to whether absentee balloting is feasible for specific employees, given the likelihood that such an approach would prove time-consuming and would give rise to increased litigation. The Board is therefore instead inclined to adopt a procedure that simply specifies that the Regional Director ''shall provide absentee mail ballots for eligible voters or individuals permitted to vote subject to challenge who are on military leave upon timely notice from any party or person that such voters or individuals will otherwise be unable to vote in the election.''

With respect to notification and the timeliness thereof, the Board's initial inclination is, as just set forth, to provide that absentee ballots will be provided upon notice ''from any party or person.'' As a threshold matter, the Board is of the view that it would indeed be impracticable to require regional directors to investigate and identify employees on military leave in each case; such an approach would almost certainly overburden regional personnel. The Board also believes that it would be unfair to adopt a rule requiring those employees on military leave to secure their own absentee ballots. The Board is generally of the view that the parties will be in the best position to know if there are employees in the unit that are (or will be) on military leave, and that they are also best positioned to inform the Board that absentee ballots will be required. The Board has considered whether the burden of identifying personnel on military leave should be allocated to a specific party, but is inclined, subject to comments, not to impose any such burden. Although the employer is probably best positioned to know if there are (or will be) any employees on military leave, there may be situations where an incumbent or petitioning union, or individual decertification petitioner, has earlier notice of the situation. Further, the Board's goal in adopting this amendment is to ensure that employees on military leave have maximum opportunity to participate in the election; accordingly, who informs the Board of the existence of such employees is immaterial. The Board is inclined to find that so long as timely notice is received from *someone,* the Board should furnish the employee on military leave with an absentee ballot.

On a closely related count, the Board recognizes that there may be situations in which a party is aware that an eligible employee is on military leave but does not so inform the Board, whether due to neglect, indifference, or gamesmanship. In such situations, the Board believes, subject to comments, that the party should be estopped from filing an objection based on the failure to provide the eligible employee with an absentee ballot. This is consistent with the Board's voter list requirement, which prevents an employer from filing an objection based on its own failure to comply with the requirement, as well as with the broader principle that a party cannot profit from its own misconduct. See, *e.g., Republic Electronics,* 266 NLRB 852, 853 (1983). The proposed amendment accordingly provides that ''[a] party that was aware of a person on military leave but did not timely notify the Regional Director shall be estopped from objecting to the failure to provide such person with an absentee ballot.'' By the same token, the Board has considered whether it should impose a penalty on parties that are aware, but fail to notify the Board, of eligible voters on military leave. The Board believes, subject to comment, that it is not necessary to include such a provision in the amendment because Board precedent is already clear that causing an employee to miss the opportunity to vote is objectionable. See, *e.g., Sahuaro Petroleum & Asphalt Co.,* 306 NLRB 586, 586–587 (1992).[68]

As for ''timely'' notice, the Board is of the view that there must be a point after which absentee ballots will no longer be provided. Such a cutoff point is necessary to ensure that the absentee ballot procedure does not come at the expense of promptly conducting and resolving elections. The Board's preliminary view, subject to comments, is that the cutoff point should be linked to the issuance of the decision and direction of election or the approval of the stipulated election agreement. In stipulated cases, the agreement contains the election details, at which point the parties (or other persons) will be able to determine with certainty whether there are indeed employees on military leave who will be unable to vote unless they are provided with an absentee ballot. In directed elections, regional directors have the discretion to include the election details in the decision and direction of election, though they retain the discretion to subsequently issue the election details. The 2019 amendments made the regional directors' discretion in this regard clear (the prior rules having stated that regional directors will ''ordinarily'' include the election details in the decision and direction of election), but the supplementary information to the 2019 amendments also made clear that the Board expected

[67] As noted earlier, the Board appears to have promptly disregarded *South West Pennsylvania Pipe Lines'* emphasis on the relatively small unit size and number of employees on military leave, as well as the emphasis on the parties' agreement to permit absentee balloting. In addition, certain of the procedures used under that case would likely be superfluous in light of subsequent developments. Thus, *South West Pennsylvania Pipe Lines'* concern with gathering and sharing employee addresses is likely unnecessary following the Board's adoption of the voter list requirement.

[68] The Board notes, however, that in such situations an election is set aside only if the employees prevented from voting could have affected the election results had they cast ballots. See id.

that regional directors ''should ordinarily be able to provide the election details in the direction of election.'' 84 FR 68544. In view of these considerations, as well as the fact that the voter list is due (pursuant to the 2019 amendments) 5 business days after the issuance of a decision and direction of election or approval of an election agreement, the Board is inclined to provide that any request for an absentee ballot must also be received within 5 business days of the approval of an election agreement or issuance of the decision and direction of election. But given that there may be situations where the election arrangements are unknown until some point after the issuance of a decision and direction of election, the Board is inclined to also provide that requests for absentee ballots must be received within 5 business days ''absent extraordinary circumstances.''

With respect to securing the mailing addresses of employees on military leave, the Board is inclined, subject to comments, to provide that in order to be timely, a request for an absentee ballot must not only be received within 5 business days of the direction of election or approval of an election agreement, but must also be ''accompanied by the mailing address at which the person can be reached while on leave.'' As discussed above, the Board believes that the parties—most often the employer—will already have such employees' contact information or will have a way of readily obtaining it, and in such situations the parties should simply provide it in the course of notifying the Board that absentee ballots will be needed for those employees.[69] The Board would, however, be particularly interested in the input of the Department of Defense (and any other commenters with experience in securing contact information for military personnel) with respect to how best to accomplish the goal of gathering military mailing addresses.

Finally, the Board is also of the view that there must be a provision setting forth a time after which absentee ballots will not be counted. Such a cutoff point is, like the cutoff point for notifying the Board of employees on military leave, necessary to prevent the absentee ballot procedure from unduly delaying the finality of election results. The Board is of the preliminary view that the cutoff point for counting absentee mail ballots should be tied to the date on which they are mailed to the employees, and that 30 calendar days should, in most circumstances, provide enough time for the absentee ballot to be delivered to the employee, filled out, and returned to the region. The Board recognizes, however, that this will often create situations when the election has been conducted but the period for receiving absentee ballots has not yet passed. The Board is of the view that where absentee ballots remain outstanding when the ballots would otherwise be counted (usually at the end of manual polling periods), the region should conduct the count as usual, but the tally of ballots should include a tabulation for outstanding absentee ballots. In the event the outstanding absentee ballots could not be determinative, the tally of ballots will be considered final; if the absentee ballots could be determinative, the region will wait until the 30-day period has elapsed, after which the region will determine whether the absentee ballots received (if any) since the initial tally of ballots are sufficient in number to affect the result. If so, the Regional Director will open and count such ballots and issue a revised tally of ballots; if not, the initial tally of ballots will be deemed final.

The Board believes that by adopting these or similar procedures, absentee ballots for military personnel can be provided without sacrificing the prompt conduct and conclusion of elections. Under the proposed amendment, the election itself will not be delayed, nor will the ballot count; the likely worst-case scenario is that the final tally of ballots will be delayed by several days in order to wait for and count outstanding determinative absentee ballots. The Board also believes that these or similar procedures will minimize or avoid the types of considerations that may otherwise favor prohibiting absentee balloting, such as those identified by the Third Circuit in *Cedar Tree,* 169 F.3d at 797–798. First, by limiting absentee ballots to employees on military leave, the Board believes that only a subset of all representation cases will be affected, avoiding logistical costs and concerns that would follow if the Board provided for absentee balloting by other categories of employees. Likewise, a blanket rule that absentee ballots will be provided to employees on military leave when timely requested avoids time-consuming individualized determinations as to whether an absentee ballot should be provided in a given case. In this regard, the proposed amendment will be predictable and even-handed. And finally, the proposed amendment will not result in the postponement of vote counts, but only (at worst) a modest delay in the issuance of a final tally of ballots.

[69] To the extent employers use the voter list to notify the Regional Director of the need for absentee ballots for employees on military leave, the Board is proposing that the voter list must include the employee's mailing address while on leave *in addition to* the employee's home address. The Board acknowledges that there may be situations in which a home address alone will be sufficient to provide the voter on military leave with an absentee ballot, including where the military leave involved is short-term.

IV. Regulatory Procedures

The Regulatory Flexibility Act

A. Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act of 1980 (''RFA''), 5 U.S.C. 601 *et seq.,* ensures that agencies ''review draft rules to assess and take appropriate account of the potential impact on small businesses, small governmental jurisdiction, and small organizations, as provided by the [RFA].'' [70] It requires agencies promulgating proposed rules to prepare an Initial Regulatory Flexibility Analysis (''IRFA'') and to develop alternatives wherever possible, when drafting regulations that will have a significant impact on a substantial number of small entities.[71] However, an agency is not required to prepare an IRFA for a proposed rule if the agency head certifies that, if promulgated, the rule will not have a significant economic impact on a substantial number of small entities.[72] The RFA does not define either ''significant economic impact'' or ''substantial number of small entities.'' [73] Additionally, ''[i]n the absence of statutory specificity, what is 'significant' will vary depending on the economics of the industry or sector to be regulated. The agency is in the best position to gauge the small entity impacts of its regulations.'' [74]

As discussed below, the Board is uncertain whether its proposed rule will have a significant economic impact on a substantial number of small entities. The Board assumes for purposes of this analysis that a substantial number of small employers and small entity labor unions will be impacted by this rule because at a minimum, they will need to review and understand the effect of

[70] E.O. 13272, Sec. 1, 67 FR 53461 (''Proper Consideration of Small Entities in Agency Rulemaking'').

[71] Under the RFA, the term ''small entity'' has the same meaning as ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' 5 U.S.C. 601(6).

[72] 5 U.S.C. 605(b).

[73] 5 U.S.C. 601.

[74] Small Business Administration Office of Advocacy, ''A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act'' (''SBA Guide'') at 18, *https://www.sba.gov/sites/default/files/advocacy/How-to-Comply-with-the-RFA-WEB.pdf.*

the changes to the voter list requirement and the provision of absentee ballots to employees on military leave. Additionally, there may be compliance costs that are unknown to the Board.

For these reasons, the Board has elected to prepare an IRFA to provide the public the fullest opportunity to comment on the proposed rule.[75] An IRFA describes why an action is being proposed; the objectives and legal basis for the proposed rule; the number of small entities to which the proposed rule would apply; any projected reporting, recordkeeping, or other compliance requirements of the proposed rule; any overlapping, duplicative, or conflicting Federal rules; and any significant alternatives to the proposed rule that would accomplish the stated objectives, consistent with applicable statutes, and that would minimize any significant adverse economic impacts of the proposed rule on small entities.[76] An IRFA also presents an opportunity for the public to provide comments that will shed light on potential compliance costs that are unknown to the Board or on any other part of the IRFA.

Detailed descriptions of this proposed rule, its purpose, objectives, and the legal basis are contained earlier in the **SUMMARY** and **SUPPLEMENTARY INFORMATION** sections. In brief, the proposed rule includes two provisions. First, in order to better protect employee privacy interests, the proposed rule modifies the current voter list provisions to eliminate the requirement that the employer provide ''available personal email addresses'' and ''available home and personal cellular ('cell') telephone numbers'' of all eligible voters (including individuals permitted to vote subject to challenge) to the Regional Director and the other parties. Second, the proposed rule establishes a procedure to provide absentee ballots to employees on military leave in order to maximize their opportunity to participate in Board-conducted elections.

B. Description and Estimate of Number of Small Entities to Which the Rule Applies

To evaluate the impact of the proposed rule, the Board first identified the universe of small entities that could be impacted by the changes to the voter list requirement and by the introduction of absentee balloting by employees on military leave.

Both changes will apply to all entities covered by the National Labor Relations Act (''NLRA'' or ''the Act''). According to the United States Census Bureau, there were 5,954,684 businesses with employees in 2016.[77] Of those, 5,934,985 were small businesses with fewer than 500 employees.[78] Although the proposed rule would only apply to employers who meet the Board's jurisdictional requirement, the Board does not have the means to calculate the number of small businesses within the Board's jurisdiction.[79] Accordingly, the Board assumes for purposes of this analysis that the great majority of the 5,934,985 small businesses could be impacted by the proposed rule.

These two changes will also impact all labor unions, as organizations representing or seeking to represent employees. Labor unions, as defined by the NLRA, are entities ''in which employees participate and which exist for the purpose . . . of dealing with employers concerning grievances, labor disputes, wages, rates of pay, hours of employment, or conditions of work.'' [80] The Small Business Administration's (''SBA'') ''small business'' standard for ''Labor Unions and Similar Labor Organizations'' is $7.5 million in annual receipts.[81] In 2012, there were 13,740 labor unions in the U.S.[82] Of these unions, 11,245 had receipts of less than $1,000,000; 2,022 labor unions had receipts between $1,000,000 and $4,999,999; and 141 had receipts between $5,000,000 and $7,499,999. In aggregate, 13,408 labor unions (97.6% of total) are small businesses according to SBA standards.

The proposed change to the voter list requirement will only be applied as a matter of law under certain circumstances in Board proceedings, namely, when a petition has been filed pursuant Section 9(c) of the Act and the Regional Director, based on that petition, has either approved an election agreement or directed an election. Therefore, the frequency with which the issue arises is indicative of the number of small entities most directly impacted by the proposed rule. For example, in Fiscal Year 2019, 1,179 petitions were filed and proceeded to an election.[83] Each of these elections involved at least one employer and at least one labor union, but even so, this is only a de minimis amount of all small entities under the Board's jurisdiction.

Similarly, the number of small entities expected to be impacted by the provision of absentee ballots for military personnel is also low. Although in theory each party to an election could be affected by this proposed change, it is unlikely that every Board-conducted election will require absentee ballots for military personnel. But even if every election were to require such ballots, the number of parties involved is once again only a de minimis amount of all small entities under the Board's jurisdiction.

C. Recordkeeping, Reporting, and Other Compliance Costs

The RFA requires agencies to consider the direct burden that compliance with a new regulation will likely impose on

[75] After a review of the comments, the Board may elect to certify that the rule will not have a significant economic impact on a substantial number of small entities in the publication of the final rule. 5 U.S.C. 605(b).

[76] 5 U.S.C. 603(b).

[77] See U.S. Department of Commerce, Bureau of Census, 2016 Statistics of U.S. Businesses (''SUSB'') Annual Data Tables by Establishment Industry, *https://www.census.gov/data/tables/2016/econ/susb/2016-susb-annual.html* (from downloaded Excel Table titled ''U.S., 6-digit NAICS'').

[78] Id. The Census Bureau does not specifically define ''small business'' but does break down its data into firms with fewer than 500 employees and those with 500 or more employees. Consequently, the 500-employee threshold is commonly used to describe the universe of small employers. For defining small businesses among specific industries, the standards are defined by the North American Industry Classification System (NAICS).

[79] Pursuant to 29 U.S.C. 152(6) and (7), the Board has statutory jurisdiction over private sector employers whose activity in interstate commerce exceeds a minimal level. *NLRB* v. *Fainblatt.* 306 U.S. 601, 606–607 (1939). To this end, the Board has adopted monetary standards for the assertion of jurisdiction that are based on the volume and character of the business of the employer. In general, the Board asserts jurisdiction over employers in the retail business industry if they have a gross annual volume of business of $500,000 or more. *Carolina Supplies & Cement Co.,* 122 NLRB 88 (1959). But shopping center and office building retailers have a lower threshold of $100,000 per year. *Carol Management Corp.,* 133 NLRB 1126 (1961). The Board asserts jurisdiction over non-retailers generally where the value of goods and services purchased from entities in other states is at least $50,000. *Siemons Mailing Service,* 122 NLRB 81 (1959).

The following employers are excluded from the NLRB's jurisdiction by statute:

—Federal, state and local governments, including public schools, libraries, and parks, Federal Reserve banks, and wholly-owned government corporations. 29 U.S.C. 152(2).

—employers that employ only agricultural laborers, those engaged in farming operations that cultivate or harvest agricultural commodities or prepare commodities for delivery. 29 U.S.C. 152(3).

—employers subject to the Railway Labor Act, such as interstate railroads and airlines. 29 U.S.C. 152(2).

[80] 29 U.S.C. 152(5).

[81] See 13 CFR 121.201.

[82] The Census Bureau only provides data about receipts in years ending in 2 or 7. The 2017 data has not been published, so the 2012 data is the most recent available information regarding receipts. See U.S. Department of Commerce, Bureau of Census, 2012 SUSB Annual Data Tables by Establishment Industry, *https://www2.census.gov/programs-surveys/susb/tables/2012/us_6digitnaics_r_2012.xlsx* (Classification #813390—Labor Unions and Similar Labor Organizations).

[83] ''Number of Elections Held in FY19,'' *https://www.nlrb.gov/news-outreach/graphs-data/petitions-and-elections/number-elections-held-fy17.*

small entities.[84] Thus, the RFA requires the Board to determine the amount of ''reporting, recordkeeping and other compliance requirements'' imposed on small entities.[85]

The Board concludes that the proposed rule imposes no capital costs for equipment needed to meet the regulatory requirements; no lost sales and profits resulting from the proposed rule; no changes in market competition as a result of the proposed rule and its impact on small entities or specific submarkets of small entities; and no costs of hiring employees dedicated to compliance with regulatory requirements.[86]

Small entities may incur some costs from reviewing the rule in order to understand the substantive changes. To become generally familiar with the revised voter list requirements and the military absentee ballot procedure, the Board estimates that a human resources specialist at a small employer or labor union may take at most ninety minutes to read the rule. It is also possible that a small employer or labor union may wish to consult with an attorney, which the Board estimates will require one hour. Using the Bureau of Labor Statistics' estimated wage and benefit costs, the Board has assessed these labor costs to be $147.12.[87]

The Board does not foresee any additional compliance costs related to eliminating the required disclosure of available personal email addresses and telephone numbers of employees and other individuals included on the voter list. For small employers, existing compliance costs are limited to gathering the required information (including available email addresses and telephone numbers), placing it in the proper format, and serving it on the Regional Director and the other parties within the required timeframe. The Board believes that removing the required disclosure of email addresses and telephone numbers will reduce existing compliance costs for small employers. There are no existing compliance costs for small unions with respect to the voter list requirement; they are merely obligated to refrain from misusing the list or the information contained therein. Removing email addresses and phone numbers from the list may result in some additional costs to small unions, who will now need to gather such information themselves or, failing that, resort to other methods of contacting eligible voters, but such costs do not involve compliance with the proposed change itself. Should a commenter provide data demonstrating the cost of eliminating provision of personal email addresses and telephone numbers, the Board will consider that information.

The Board also believes that any additional compliance costs related to the provision of absentee ballots to employees on military leave will be de minimis. As proposed, all a party need do to comply with the change is timely inform the Board when it is aware of such voters; parties are not required to affirmatively ascertain whether such voters exist. A party's failure to comply may in some circumstances give rise to objections, related litigation, and potentially a second election, but the cost of compliance itself is merely the de minimis cost of telling the Board what the party knows with regard to employees on military leave when the party knows it. The proposed change may result in some situations where a final tally of ballots is delayed due to outstanding dispositive absentee ballots, but the Board does not think that such delay will result in additional costs because once the final tally of ballots issues, parties will have the usual allotted time to file objections. It is possible that the absentee balloting procedure may itself give rise to additional litigation surrounding whether absentee ballots were timely requested and/or provided to the absentee voter, improperly denied or provided, or whether late-arriving absentee ballots should have been counted. But the Board's proposed procedure addresses these contingencies and should accordingly minimize this type of litigation and the costs associated with it. Should a commenter provide data demonstrating the cost of instituting an absentee ballot procedure for employees on military leave, the Board will consider that information.

D. Overall Economic Impacts

The Board does not find the estimated, quantifiable cost of reviewing and understanding the rule—$147.12 for small employers and unions—to be significant within the meaning of the RFA.

In making this finding, one important indicator is the cost of compliance in relation to the revenue of the entity or the percentage of profits affected.[88] Other criteria to be considered are the following:

—Whether the rule will cause long-term insolvency, *i.e.,* the regulatory costs that may reduce the ability of the firm to make future capital investment, thereby severely harming its competitive ability, particularly against larger firms;

—Whether the cost of the proposed regulation will (a) eliminate more than 10 percent of the businesses' profits; (b) exceed one percent of the gross revenues of the entities in a particular sector; or (c) exceed five percent of the labor costs of the entities in the sector.[89]

The minimal cost to read and understand the rule will not generate any such significant economic impacts.

Since the only quantifiable impact that the Board has identified is the $147.12 that may be incurred in reviewing and understanding the rule, the Board does not believe there will be a significant economic impact on a substantial number of small entities associated with this proposed rule. The Board welcomes input from the public regarding additional costs of compliance not identified by the Board or costs of compliance the Board identified but lacks the means to accurately estimate.

E. Duplicate, Overlapping, or Conflicting Federal Rules

Agencies are required to include in an IRFA ''all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.'' [90] The Board has not identified any such federal rules, but welcomes comments that suggest any potential conflicts not noted in this section.

F. Alternatives Considered

Pursuant to 5 U.S.C. 603(c), agencies are directed to look at ''any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant impact of the proposed rule on small entities.'' Specifically, agencies must consider establishing different compliance or reporting requirements or timetable for small entities, simplifying compliance and reporting for small entities, using performance rather than design

[84] See *Mid-Tex Elec. Co-op* v. *FERC,* 773 F.2d 327, 342 (D.C. Cir. 1985) (''[I]t is clear that Congress envisioned that the relevant 'economic impact' was the impact of compliance with the proposed rule on regulated small entities.'').

[85] See 5 U.S.C. 603(b)(4), 604(a)(4).

[86] SBA Guide at 37.

[87] For wage figures, see May 2017 National Occupancy Employment and Wage Estimates, found at *https://www.bls.gov/oes/current/oes_nat.htm.* The Board has been administratively informed that BLS estimates that fringe benefits are approximately equal to 40 percent of hourly wages. Thus, to calculate total average hourly earnings, BLS multiplies average hourly wages by 1.4. In May 2017, average hourly wages for a Human Resources Specialist (BLS #13–1071) were $31.84. The same figure for a lawyer (BLS #13–1011) was $57.33. Accordingly, the Board multiplied each of those wage figures by 1.4 and added them to arrive at its estimate.

[88] See SBA Guide at 18.

[89] Id. at 19.

[90] 5 U.S.C. 603(b)(5).

standards, and exempting small entities from any part of the rule.[91]

First, the Board considered taking no action. Inaction would leave in place the current voter list requirements and would not provide absentee ballots for employees on military leave. However, for the reasons stated in Section I through III, the Board finds it desirable to revisit these policies and to do so through the rulemaking process. Consequently, the Board rejects maintaining the status quo.

Second, the Board considered creating exemptions for certain small entities. This was rejected as impractical, considering that exemptions for small entities would substantially undermine the purposes of the proposed rule because such a large percentage of employers and unions would be exempt under the SBA definitions. Specifically, to exempt small entities from the decision to eliminate the required disclosure of available personal email addresses and telephone numbers from the voter list would leave the employees of most small entities with inadequate protection of their privacy interests and would in fact penalize small employers by requiring them to disclose more contact information than would be required of other employers. And to exempt small entities from the provision of absentee ballots to employees on military leave would be contrary to the purposes of the rule: To maximize the opportunity such employees have to participate in Board-conducted elections.

Moreover, given the very small quantifiable cost of compliance, it is possible that the burden on a small business of determining whether it fell within an exempt category might exceed the burden of compliance. Congress gave the Board very broad jurisdiction, with no suggestion that it wanted to limit the coverage of any part of the Act to only larger employers. As the Supreme Court has noted, ''[t]he [NLRA] is federal legislation, administered by a national agency, intended to solve a national problem on a national scale.'' [92]

Because no alternatives considered will accomplish the objectives of this proposed rule while minimizing costs for small businesses, the Board believes that proceeding with this rulemaking is the best regulatory course of action. The Board welcomes public comment on any facet of this IRFA, including alternatives that it has failed to consider.

Paperwork Reduction Act

The NLRB is an agency within the meaning of the Paperwork Reduction Act (''PRA''). 44 U.S.C. 3502(1) and (5). The PRA creates rules for agencies for the ''collection of information,'' 44 U.S.C. 3507, which is defined as ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format.'' 44 U.S.C. 3502(3)(A). Collections of information that occur ''during the conduct of an administrative action or investigation involving an agency against specific individuals or entities'' are exempt from the PRA. 44 U.S.C. 3518(c)(1)(B)(ii); 5 CFR 1320.4(a)(2).

As a preliminary matter, the elimination of the required provision of available personal telephone numbers and email addresses in the voter list does not require any collection of information—indeed, it reduces the information collected—so the PRA does not apply.

Aside from that circumstance, the changes contained in this proposed rule are exempt from the PRA because any potential collection of information would take place in the context of a representation proceeding, which is an administrative action within the meaning of the PRA. As the Board noted in its 2014 rulemaking, the Senate Report on the PRA makes it clear that the exemption in ''Section 3518(c)(1)(B) is not limited to agency proceedings of a prosecutorial nature but also include[s] any agency proceeding involving specific adversary parties.'' 79 FR 74468 (quoting S. Rep. No. 96–930, at 56 (1980)). See also 5 CFR 1320.4(c) (OMB regulation interpreting the PRA, providing that exemption applies ''after a case file or equivalent is opened with respect to a particular party''). As the Board explained in its 2014 rulemaking, ''[a] representation proceeding is . . . 'against specific individuals or entities' within the meaning of section 3518(c)(1)(B)(ii),'' and the outcome is binding on and thereby alters the legal rights of those parties. See 79 FR 74469. The proposed changes will apply within representation proceedings, and thus are administrative actions involving specific parties and fall within the PRA exemption.[93]

Accordingly, the proposed rules do not contain information collection requirements that require approval of the Office of Management and Budget under the PRA.

List of Subjects in 29 CFR Part 102

Administrative practice and procedure, Claims, Equal access to justice, Freedom of information, Income taxes, Labor management relations, Lawyers, Privacy, Reporting and recordkeeping requirements, Sunshine Act.

Text of the Proposed Rule

For the reasons discussed in the preamble, the Board proposes to amend 29 CFR part 102 as follows:

PART 102—RULES AND REGULATIONS, SERIES 8

■ 1. The authority citation for part 102 continues to read as follows:

Authority: Sections 1, 6, National Labor Relations Act (29 U.S.C. 151, 156). Section 102.117 also issued under section 552(a)(4)(A) of the Freedom of Information Act, as amended (5 U.S.C. 552(a)(4)(A)), and Section 102.117a also issued under section 552a(j) and (k) of the Privacy Act of 1974 (5 U.S.C. 552a(j) and (k)). Sections 102.143 through 102.155 also issued under section 504(c)(1) of the Equal Access to Justice Act, as amended (5 U.S.C. 504(c)(1)).

■ 2. Revise § 102.62(d) to read as follows:

§ 102.62 Election agreements; voter list; Notice of Election.

* * * * *

(d) *Voter list.* Absent agreement of the parties to the contrary specified in the election agreement or extraordinary circumstances specified in the direction of election, within 5 business days after the approval of an election agreement pursuant to paragraph (a) or (b) of this section, or issuance of a direction of election pursuant to paragraph (c) of this section, the employer shall provide to the Regional Director and the parties named in the agreement or direction a list of the full names, work locations, shifts, job classifications, and home addresses of all eligible voters. The employer shall also include in separate sections of that list the same information for those individuals who will be permitted to vote subject to challenge. In order to be timely filed and served, the list must be received by the Regional Director and the parties

[91] 5 U.S.C. 603(c).

[92] *NLRB* v. *Natural Gas Utility Dist. of Hawkins County,* 402 U.S. 600, 603–604 (1971) (quotation omitted).

[93] As acknowledged in the Initial Regulatory Flexibility Analysis above, the provision for absentee ballots to employees on military leave may result in litigation that may in turn result in rerun elections, and such litigation would not have been conducted and such elections would not have been held under the prior policy of not permitting absentee ballots. Nonetheless, particular collections of information required during the course of an election proceeding are not attributable to the instant proposed rule; instead, such requirements flow from prior rules. And in any event, even if such collections of information were attributable to this proposed rule, an election is a representation proceeding and therefore exempt from the PRA.

named in the agreement or direction respectively within 5 business days after the approval of the agreement or issuance of the direction unless a longer time is specified in the agreement or direction. The list of names shall be alphabetized (overall or by department) and be in an electronic format approved by the General Counsel unless the employer certified that it does not possess the capacity to produce the list in the required form. When feasible, the list shall be filed electronically with the Regional Director and served electronically on the other parties named in the agreement or direction. A certificate of service on all parties shall be filed with the Regional Director when the voter list is filed. The employer's failure to file or serve the list within the specified time or in proper format shall be grounds for setting aside the election whenever proper and timely objections are filed under the provisions of § 102.69(a)(8). The employer shall be estopped from objecting to the failure to file or serve the list within the specified time or in the proper format if it is responsible for the failure. The parties shall not use the list for purposes other than the representation proceeding, Board proceedings arising from it, and related matters.

* * * * *

■ 3. Revise § 102.67(l) to read as follows:

§ 102.67 Proceedings before the Regional Director; further hearing; action by the Regional Director; appeals from actions of the Regional Director; statement in opposition; requests for extraordinary relief; Notice of Election; voter list.

* * * * *

(l) *Voter list.* Absent extraordinary circumstances specified in the direction of election, the employer shall, within 5 business days after issuance of the direction, provide to the Regional Director and the parties named in such direction a list of the full names, work locations, shifts, job classifications, and home addresses of all eligible voters. The employer shall also include in separate sections of that list the same information for those individuals who will be permitted to vote subject to challenge. In order to be timely filed and served, the list must be received by the Regional Director and the parties named in the direction respectively within 5 business days after issuance of the direction of election unless a longer time is specified therein. The list of names shall be alphabetized (overall or by department) and be in an electronic format approved by the General Counsel unless the employer certifies that it does not possess the capacity to produce the list in the required form. When feasible, the list shall be filed electronically with the Regional Director and served electronically on the other parties named in the direction. A certificate of service on all parties shall be filed with the Regional Director when the voter list is filed. The employer's failure to file or serve the list within the specified time or in proper format shall be grounds for setting aside the election whenever proper and timely objections are filed under the provisions of § 102.69(a)(8). The employer shall be estopped from objecting to the failure to file or serve the list within the specified time or in the proper format if it is responsible for the failure. The parties shall not use the list for purposes other than the representation proceeding, Board proceedings arising from it, and related matters.

■ 4. Revise § 102.69(a)(1), (2), and (7) to read as follows:

§ 102.69 Election procedure; tally of ballots; objections; certification by the Regional Director; hearings; Hearing Officer reports on objections and challenges; exceptions to Hearing Officer reports; Regional Director decisions on objections and challenges.

(a) *Election procedure; tally; objections.* (1) Unless otherwise directed by the Board, all elections shall be conducted under the supervision of the Regional Director in whose Region the proceeding is pending.

(2) All elections shall be by secret ballot. The Regional Director shall provide absentee mail ballots for eligible voters or individuals permitted to vote subject to challenge who are on military leave upon timely notice from any party or person that such voters or individuals will otherwise be unable to vote in the election. Absent extraordinary circumstances, such notification will be timely if received by the Regional Director within 5 business days of the direction of election or approval of election agreement, and if accompanied by the mailing address at which the person can be reached while on leave. This paragraph (a)(2) does not in any way modify the requirement that the employer provide the voter list information required in § 102.62(d) or § 102.67(l). A party that was aware of a person on military leave but did not timely notify the Regional Director shall be estopped from objecting to the failure to provide such person with an absentee ballot. Absentee ballots must be returned to and received at the regional office within 30 calendar days from the date they are mailed to the employees by the Regional Director.

* * * * *

(7) Upon conclusion of the election the ballots will be counted and a tally of ballots prepared and immediately made available to the parties. If the Regional Director has provided absentee ballots to employees on military leave, the time for returning such ballots remains open at the conclusion of the election, and absentee ballots remain outstanding, the tally of ballots shall include the number of absentee ballots that remain outstanding. If the outstanding absentee ballots are potentially dispositive, after the time for returning absentee ballots has passed the Regional Director shall determine whether the number of outstanding absentee ballots received since the initial tally of ballots is dispositive; if so, the Regional Director shall open and count any absentee ballots received since the election, and shall issue a revised tally of ballots. If the number of outstanding absentee ballots received since the initial tally of ballots is not dispositive, the initial tally of ballots shall be deemed final.

* * * * *

Dated: July 15, 2020.

Roxanne L. Rothschild,

Executive Secretary, National Labor Relations Board.

[FR Doc. 2020–15596 Filed 7–28–20; 8:45 am]

BILLING CODE 7545–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2020–0356; FRL–10012–14–Region 7]

Air Plan Approval; Missouri; Removal of Control of Emissions From Polyethylene Bag Sealing Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing approval of a State Implementation Plan (SIP) revision submitted by the State of Missouri on January 15, 2019, and supplemented by letter on July 11, 2019. Missouri requests that the EPA remove a rule related to the control of emissions from polyethylene bag sealing operations in the St. Louis, Missouri area from its SIP. This removal does not have an adverse effect on air quality. The EPA's proposed approval of this rule revision is in accordance with the requirements of the Clean Air Act (CAA).

DATES: Comments must be received on or before August 28, 2020.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–R07–OAR–2020–0356 to *https://www.regulations.gov.* Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received will be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Written Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Peter, Environmental Protection Agency, Region 7 Office, Air Permitting and Standards Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7397; email address: *peter.david@epa.gov.*

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

Table of Contents

I. Written Comments

Submit your comments, identified by Docket ID No. EPA–R07–OAR–2020–0356 at *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. What is being addressed in this document?

The EPA is proposing to approve the removal of 10 Code of State Regulations (CSR) 10–5.360, *Control of Emissions from Polyethylene Bag Sealing Operations,* from the Missouri SIP.

According to the July 11, 2019 letter from the Missouri Department of Natural Resources, available in the docket for this proposed action, Missouri rescinded the rule because, of the only two facilities that were initially subject to the rule, neither facility is currently subject to the rule. One facility shutdown and the other facility no longer meets the applicability of the rule, specifically the facility no longer has a potential-to-emit (PTE) of volatile organic compounds (VOC) greater than 100 tons per year (tpy). Therefore, the rule is no longer necessary for attainment and maintenance of the 1979, 1997, 2008, or 2015 National Ambient Air Quality Standards (NAAQS) for Ozone.

III. Background

The EPA established a 1-hour ozone NAAQS in 1971. 36 FR 8186 (April 30, 1971). On March 3, 1978, the entire St. Louis Air Quality Control Region (AQCR) (070) was identified as being in nonattainment of the 1971 1-hour ozone NAAQS, as required by the CAA Amendments of 1977. 43 FR 8962 (March 3, 1978). On the Missouri side, the St. Louis nonattainment area included the city of St. Louis and Jefferson, St. Charles, Franklin and St. Louis Counties (hereinafter referred to in this document as the ''St. Louis Area''). On February 8, 1979, the EPA revised the 1-hour ozone NAAQS, referred to as the 1979 ozone NAAQS. 44 FR 8202 (February 8, 1979). On May 26, 1988, the EPA notified Missouri that the SIP was substantially inadequate (hereinafter referred to as the ''SIP Call'') to attain the 1-hour ozone NAAQS in the St. Louis Area. *See* 54 FR 43183 (October 23, 1989). To address the inadequacies identified in the SIP Call, Missouri submitted VOC control regulations on June 14, 1985; November 19, 1986; and March 30, 1989. The EPA subsequently approved the revised control regulations for the St. Louis Area on March 5, 1990. The VOC control regulations approved by EPA into the SIP included reasonably available control technology (RACT) rules as required by CAA section 172(b)(2), including 10 CSR 10–5.360 *Control of Emissions from Polyethylene Bag Sealing Operations.*

The EPA redesignated the St. Louis Area to attainment of the 1979 1-hour ozone standard on May 12, 2003. 68 FR 25418. Pursuant to section 175A of the CAA, the first 10-year maintenance period for the 1-hour ozone standard began on May 12, 2003, the effective date of the redesignation approval. On April 30, 2004, the EPA published a final rule in the **Federal Register** stating the 1-hour ozone NAAQS would no longer apply (*i.e.,* would be revoked) for an area one year after the effective date of the area's designation for the 8-hour ozone NAAQS. 69 FR 23951 (April 30, 2004). The effective date of the revocation of the 1979 1-hour ozone standard for the St. Louis Area was June 15, 2005. *See* 70 FR 44470 (August 3, 2005).

As noted above, 10 CSR 10–5.360, *Control of Emissions from Polyethylene Bag Sealing Operations,* was approved into the Missouri SIP as a RACT rule on March 5, 1990.[1] 55 FR 7712 (March 5, 1990). At the time the rule was approved into the SIP, 10 CSR 10–5.360 applied to all installations throughout St. Louis City and Jefferson, St. Charles, Franklin and St. Louis Counties that utilized polyethylene bag sealing operations.

By letter dated January 15, 2019, Missouri requested that the EPA remove 10 CSR 10–5.360 from the SIP. Section 110(l) of the CAA prohibits EPA from approving a SIP revision that interferes with any applicable requirement concerning attainment and reasonable further progress (RFP), or any other applicable requirement of the CAA. The State supplemented its SIP revision with a July 11, 2019 letter in order to address the requirements of section 110(l) of the CAA.

IV. What is the EPA's analysis of Missouri's SIP revision request?

In its July 11, 2019 letter, Missouri states that it intended its RACT rules, such as 10 CSR 10–5.360, to solely apply to existing sources in accordance with section 172(c)(1) of the CAA.[2] Missouri states that although the applicability section of 10 CSR 10–5.360 specifies that the rule applies to all installations located throughout St.

[1] 10 CSR 10–5.360 was initially approved into Missouri's SIP on October 15, 1984 (49 FR 40164) but was ultimately revised as part of the updated control strategy and this revision was approved on March 5, 1990.

[2] The EPA agrees with Missouri's interpretation of CAA section 172(c)(1) in regard to whether RACT is required for existing sources, but also notes that the State regulation establishing RACT may apply to new sources as well, dependent upon the State regulation's language.

Louis City and Jefferson, St. Charles, Franklin and St. Louis Counties, the only two facilities that met the applicability criteria of the rule were Bemis Bag Company and Crown Zellerbach (Gaylord Container) which is currently being operated as International Paper St. Louis (hereinafter referred to as ''Bemis'' and ''International Paper'', respectively).

Missouri, in its July 11, 2019 letter, indicated that Bemis is no longer in operation. The EPA confirmed that Bemis is no longer in operation [3] and is therefore no longer subject to 10 CSR 10–5.360. Missouri further indicated in the July 11, 2019 letter that International Paper was not operating under a Part 70/Title V Operating Permit.[4] Facilities with a PTE greater than or equal to 100 tpy are required to obtain a Part 70/Title V Operating Permit.[5] To be subject to 10 CSR 10–5.360, the facility must also have a PTE greater than or equal 100 tpy. Since the PTE from International Paper does not exceed 100 tpy, the facility is no longer subject to 10 CSR 10–5.360.[6]

As stated above, Missouri contends that 10 CSR 10–5.360 may be removed from the SIP because section 172(c)(1) of the CAA requires RACT for existing sources, and because 10 CSR 10–5.360 was applicable to only two sources [7] that are no longer subject to the rule and, therefore, the rule no longer reduces VOC emissions. Because these two facilities are no longer subject to the rule, the EPA believes the rule no longer provides an emission reduction benefit to the St. Louis Area and is proposing to remove it from the SIP.

[3] The EPA reviewed MDNR's website that lists active, issued permits to facilities in Missouri and did not observe a permit for Bemis. Further, the EPA reviewed EPA's ICIS-Air database which indicated that the facility was no longer in operation.

[4] Missouri confirmed the operating permit status in an email from Shelly Reimer of MDNR to David Peter of EPA Region 7 dated June 12, 2020, which is included in the rulemaking docket. Missouri further indicated in this email that the highest annual emissions from the facility from 2003 to 2019 was approximately 3 tons. The EPA reviewed MDNR's website that lists active, issued permits and did not observe a permit for the International Paper.

[5] 10 CSR 10–6.065(2)(R).

[6] In Missouri's June 12, 2020 email, Missouri further indicated that the construction permits issued to the facility showed no indication of polyethylene bag sealing operations. International Paper would be required to obtain the appropriate construction permits before starting up any new polyethylene bag sealing operations.

[7] The EPA indicated in the February 3, 1983 **Federal Register** document (48 FR 5022), which proposed to approve 10 CSR 10–5.360 into Missouri's SIP, that two facilities were subject to this rule but did not specifically name the two facilities.

Missouri's July 11, 2019 letter states that any new sources or major modifications of existing sources are subject to new source review (NSR) permitting. Under NSR, a new major source or major modification of an existing source with a PTE of 250 tpy [8] or more of any NAAQS pollutant is required to obtain a Prevention of Significant Deterioration (PSD) permit when the area is in attainment or unclassifiable, which requires an analysis of Best Available Control Technology (BACT) in addition to an air quality analysis and an additional impacts analysis. Sources with a PTE greater than 100 tpy, but less than 250 tpy,[9] are required to obtain a minor permit in accordance with Missouri's New Source Review permitting program, which is approved into the SIP.[10] Further, a new major source or major modification of an existing source with a PTE of 100 tpy or more of any NAAQS pollutant is required to obtain a nonattainment (NA) NSR permit when the area is in nonattainment, which requires an analysis of Lowest Achievable Emission Rate (LAER) in addition to an air quality analysis, an additional impacts analysis and emission offsets. The EPA agrees with this analysis.

Missouri has demonstrated that removal of 10 CSR 10–5.360 will not interfere with attainment of the NAAQS, RFP [11] or any other applicable requirement of the CAA because the two sources ever subject to the rule are no longer subject and the removal of the rule will not cause VOC emissions to increase. Therefore, the EPA proposes to approve the removal of 10 CSR 10–5.360 from the SIP.

V. Have the requirements for approval of a SIP revision been met?

The State submission has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. The State provided public notice on this SIP revision from May 15, 2018, to August 2, 2018, and received eleven comments from the EPA that related to Missouri's lack of an adequate demonstration that the rule could be removed from the SIP in accordance with section 110(l) of the CAA, whether the rule applied to new sources and other implications related to rescinding the rule. Missouri's July 11, 2019 letter and December 3, 2018 response to comments on the state rescission rulemaking addressed the EPA's comments. In addition, the revision meets the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

VI. What action is the EPA taking?

The EPA is proposing to approve Missouri's request to rescind 10 CSR 10–5.360 from the SIP because the rule applied to two facilities that are no longer subject and because the rule is not applicable to any other source. Therefore, the rule no longer serves to reduce emissions in the St. Louis Area. Furthermore, any new sources or major modifications of existing sources in the St. Louis Area are subject to NSR permitting.[12] We are processing this as a proposed action because we are soliciting comments on this proposed action. Final rulemaking will occur after consideration of any comments.

VII. Incorporation by Reference

In this document, the EPA is proposing to amend regulatory text that includes incorporation by reference. As described in the proposed amendments to 40 CFR part 52 set forth below, the EPA is proposing to remove provisions of the EPA-Approved Missouri Regulation from the Missouri State Implementation Plan, which is incorporated by reference in accordance with the requirements of 1 CFR part 51.

VIII. Statutory and Executive Order Reviews

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

[8] The PSD major source threshold for certain sources is 100 tpy rather than 250 tpy (see 40 CFR 52.21(b)(1)(i)(*a*) and 10 C.S.R. 10–6.060(8)(A)).

[9] Except for those sources with a PSD major source threshold of 100 tpy.

[10] EPA's latest approval of Missouri's NSR permitting program rule was published in the **Federal Register** on October 11, 2016. 81 FR 70025.

[11] RFP is not applicable to the St. Louis Area because for marginal ozone nonattainment areas, such as the St. Louis Area, the specific requirements of section 182(a) apply in lieu of the attainment planning requirements that would otherwise apply under section 172(c), including the attainment demonstration and reasonably available control measures (RACM) under section 172(c)(1), reasonable further progress (RFP) under section 172(c)(2), and contingency measures under section 172(c)(9).

[12] ''NSR Permitting'' includes PSD permitting in areas designated attainment and unclassifiable, NA NSR in areas designated nonattainment and minor source permitting.

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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.
- 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 the National Technology Transfer and Advancement Act (NTTA) because this rulemaking does not involve technical standards; 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).

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 in 40 CFR Part 52

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

Dated: July 13, 2020.

James Gulliford,

Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA proposes to amend 40 CFR part 52 as set forth below:

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 AA—Missouri

§ 52.1320 [Amended]

■ 2. In § 52.1320, the table in paragraph (c) is amended by removing the entry ''10–5.360'' under the heading ''Chapter 5-Air Quality Standards and Air Pollution Control Regulations for the St. Louis Metropolitan Area''.

[FR Doc. 2020–15500 Filed 7–28–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

RIN 0648–BJ18

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Amendment 21 to the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan

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

ACTION: Notice of Availability of proposed fishery management plan amendment; request for comments.

SUMMARY: The Mid-Atlantic Fishery Management Council has submitted Amendment 21 to the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan to NMFS. Amendment 21 proposes revisions to the summer flounder commercial state quota allocation percentages and the fishery management plan goals and objectives. Amendment 21 is intended to increase equity in state allocations when annual coastwide commercial quotas are at or above historical averages, while recognizing the economic reliance coastal communities have on the state allocation percentages currently in place.

DATES: Public comments must be received on or before September 28, 2020.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2020–0107, by the following method:

- *Electronic Submission:* Submit all electronic public comments via the Federal eRulemaking Portal.

1. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0107;*

2. Click the ''Comment Now!'' icon and complete the required fields; and

3. Enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by us. 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. We will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of Amendment 21, including the Environmental Impact Statement, the Regulatory Impact Review, and the Initial Regulatory Flexibility Analysis (EIS/RIR/IRFA) prepared in support of this action are available from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 North State Street, Dover, DE 19901. The supporting documents are also accessible via the internet at: *http://www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Emily Keiley, Fishery Policy Analyst, (978) 281–9116, or email: *Emily.Keiley@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The summer flounder fishery is managed cooperatively under the provisions of the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP) developed by the Mid-Atlantic Fishery Management Council and the Atlantic States Marine Fisheries Commission, in consultation with the New England Fishery Management Council. The management unit specified in the FMP includes summer flounder (*Paralichthys dentatus*) in U.S. waters of the Atlantic Ocean from the southern border of North Carolina northward to the U.S./

Canada border. States manage summer flounder within 3 nautical miles (4.83 km) of their coasts, under the Commission's plan for summer flounder. The Federal summer flounder regulations govern fishing in Federal waters of the Exclusive Economic Zone (3 to 200 nautical miles, 4.83 km to 160.93 km offshore), as well as vessels possessing a summer flounder moratorium permit, regardless of where they fish.

On September 16, 2014 (79 FR 55432), the Council published a notice of intent (NOI) to prepare an EIS for Amendment 21 to consider, in coordination with the Commission: (1) Performing a comprehensive review of all aspects of the FMP related to summer flounder; (2) updating the FMP goals and objectives for summer flounder management; and (3) modifying management strategies and measures as necessary to achieve those goals and objectives. The Council and Commission held scoping meetings during September and October of 2014 to solicit comments from the public regarding the range of commercial and recreational summer flounder management issues should be considered in the amendment.

On March 29, 2018 (83 FR 13478), the Council published a supplemental NOI announcing that the scope of the amendment would be narrowed to include only commercial summer flounder management considerations. Due to ongoing revisions to the recreational data by the Marine Recreational Information Program, the Council and Commission chose to delay development of any issues that would rely heavily on recreational data. This includes quota allocation between the commercial and recreational sectors as well as recreational management measures and strategies. The supplemental NOI identified that the commercial fishery-focused amendment would consider revisions to:

- Current qualification criteria for Federal moratorium permit holders;
- Current state-by-state allocation of commercial quota;
- List of frameworkable items in the FMP; and
- FMP goals and objectives for summer flounder.

On August 17, 2018 (83 FR 41072), the Environmental Protection Agency announced the public comment period for the Amendment 21 draft environmental impact statement (DEIS). The public comment period extended until October 12, 2018. During that time, the Council and Commission held public hearings on the DEIS in Old Lyme, Connecticut; Washington, North Carolina; Dover, Delaware; Newport News, Virginia; Buzzards Bay, Massachusetts; Narragansett, Rhode Island; Toms River, New Jersey; Berlin, Maryland; Stony Brook, New York; and via webinar.

The Council adopted Amendment 21 on March 6, 2019, and submitted the amendment to us for review on March 17, 2020.

Proposed State-by-State Allocation Approach

Amendment 21 would modify the state-by-state commercial quota allocations when the coastwide quota exceeds 9.55 million lb (4,332 mt). When the coastwide quota is 9.55 million lb (4,332 mt) or less the quota would be distributed according to the current allocations. In years when the coastwide quota exceeds 9.55 million lb (4,332 mt) any additional quota, beyond this trigger, would be distributed in equal shares to all states except Maine, Delaware, and New Hampshire, which would split 1 percent of the additional quota.

TABLE 1—PROPOSED STATE-BY-STATE ALLOCATIONS

State	Allocation of baseline quota ≤9.55 mil lb (percent)	Allocation of *additional* quota beyond 9.55 mil lb (percent)
ME	0.04756	0.333
NH	0.00046	0.333
MA	6.82046	12.375
RI	15.68298	12.375
CT	2.25708	12.375
NY	7.64699	12.375
NJ	16.72499	12.375
DE	0.01779	0.333
MD	2.03910	12.375
VA	21.31676	12.375
NC	27.44584	12.375
Total	100	100

Revised Summer Flounder FMP Goals and Objectives

The original FMP objectives were adopted via Amendment 2 to the Summer Flounder FMP in 1993 and have remained unchanged since that time. Amendment 21 revises the FMP goals and objectives. While the current FMP contains only management objectives, the proposed revisions contain three overarching goals linked to more specific objectives. The revised goals include: (1) Ensuring sustainability, of both the summer flounder stock and fishery; (2) increasing the effectiveness of management measures, through partnerships, enforcement, and data collection; and, (3) optimization of the social and economic benefits from the summer flounder stock. Additional information on these changes can be found in the FEIS.

Public Comment Instructions

The Magnuson-Stevens Fishery Conservation and Management Act allows us to approve, partially approve, or disapprove measures recommended by the Council in an amendment based on whether the measures are consistent with the fishery management plan, plan amendment, the Magnuson-Stevens Act and its National Standards, and other applicable law. The Council develops policy for its fisheries and we defer to the Council on policy decisions unless those policies are inconsistent with the Magnuson-Steven Act or other applicable law. As such, we are seeking comment on whether measures in

Amendment 21 are consistent with the Summer Flounder, Scup, and Black Sea Bass FMP, the Magnuson-Stevens Act and its National Standards, and other applicable law. Public comments on Amendment 21 and its incorporated documents may be submitted through the end of the comment period stated in this notification of availability.

A proposed rule to implement the amendment, including draft regulatory text, will also be published in the **Federal Register** for public comment. Public comments on the proposed rule received before the end of the comment period provided in this notification of availability will be considered in the approval/disapproval decision on the amendment. All comments received by September 28, 2020, whether specifically directed to Amendment 21 or the proposed rule for this amendment, will be considered in the approval/disapproval decision on the Amendment 21. Comments received after that date will not be considered in the decision to approve or disapprove the amendment. To be considered, comments must be received by close of business on the last day of the comment period.

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

Dated: July 24, 2020.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–16446 Filed 7–24–20; 4:15 pm]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 85, No. 146
Wednesday, July 29, 2020

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

July 24, 2020.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by August 28, 2020 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Operating Guidelines, Forms and Waivers.

OMB Control Number: 0584–0083.

Summary of Collection: Under Section 16 of the Food and Nutrition Act of 2008 (the Act), 7 U.S.C. 2025, the Secretary is authorized to pay each State agency an amount equal to 50 percent of all administrative costs involved in each State agency's operation of the Supplemental Nutrition Assistance Program (SNAP). Under corresponding SNAP regulations at 7 CFR 272.2(c), the State agency is required to submit and maintain annually for FNS approval a (1) Budget Projection Statement (FNS–366A), which projects total costs for major areas of SNAP operations, and (2) a Program Activity Statement (FNS–366B), which provides a summary of SNAP operations during the preceding fiscal year both approved by OMB under the Food Processing Reporting Systems (FPRS). Additionally, Under Section 11(o) of the Act each State agency is required to develop and submit plans for the use of (3) automated data processing (ADP) and information retrieval systems to administer SNAP. As for (4) State Plan of Operation Updates, State agencies will submit the operations planning documents to the appropriate regional office for approval through the SNAP The Waiver Information Management System (WIMS) (5) the Federal Financial Reporting Form SF 425 (known as SF 425/FNS 778); (6) Other ADP Plan or Updates. Additionally, to improve operational efficiency and streamline the agency's information collection portfolio, FNS is merging the recordkeeping hours for the State Issuance and Participation Estimates (FNS–388) and Supplemental Nutrition Assistance Program Project Area Data Format (FNS–388A) into this information collection and will submit a discontinuation request for 0584–0081. We are not seeking reporting burden hours for FNS 388 or 388A.

Need and Use of the Information: FNS will collect information to estimate funding needs and also provide data on the number of applications processed, number of fair hearings, and fraud control activity. FNS uses the data to estimate funding needs and to monitor State agency activity levels and performance. If the information were not collected it would disrupt budget planning and delay appropriation distributions and FNS would not be able to verify and ensure State compliance with statutory criteria. The FNS–388 and FNS–388A records State agencies are required to maintained by the same recordkeeping activities are essentially the same; three years. We are merging this information collection for operational efficiency.

Description of Respondents: State, Local or Tribal Government.

Number of Respondents: 53.

Frequency of Responses: Recordkeeping; Reporting: Annually.

Total Burden Hours: 1,124.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2020–16381 Filed 7–28–20; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

July 23, 2020.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by August 28, 2020 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the

following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Office of Communication

Title: Event Appearance Request for the Secretary or Members of his Staff.

OMB Control Number: 0506–0006.

Summary of Collection: The Office of Communication will collect information on events that the public would like the Secretary or members of his staff to participate in, or those in which the incoming Secretary or members of his staff may want to use to reach back out to interested parties to invite them to events. The following information will be collected: Organization, Address, Phone/Cell Number, First and last name of point of contact, Email Address, Type of event, Date of event, Event location, Secretary's role, Number of attendees, Press open or closed.

Need and Use of the Information: The information will be used to review, approve, delegate and regret events for the Secretary and members of his staff. The information will come from public, businesses, not-for profit organizations; state, local or tribal governments. The information will be collected daily. If the information is not collected, events would not be properly scheduled for the Secretary or member of his staff and therefore would not be able to inform the Secretary or members of his staff of incoming event requests.

Description of Respondents: Individuals; Businesses; Not-for profit; State, Local or Tribal Government.

Number of Respondents: 5,000.

Frequency of Responses: Reporting: Other.

Total Burden Hours: 2,500.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2020–16349 Filed 7–28–20; 8:45 am]

BILLING CODE 3410–13–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Kentucky Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Kentucky Advisory Committee (Committee) will hold two virtual briefings hearings to hear testimony from advocates and others on bail reform in Kentucky.

DATES: The hearings will take place on:

- (Panel II) Thursday August 20, 12 p.m.–2:00 p.m. EST
- (Panel III) Tuesday August 25, 12 p.m.–2:00 p.m. EST

Public Call Information: (both panels) Dial: 800–367–2403; Conference ID: 4778000.

FOR FURTHER INFORMATION CONTACT: Barbara Delaviez, DFO, at *bdelaviez@usccr.gov* or 202–539–8246.

SUPPLEMENTARY INFORMATION: Members of the public can listen to the discussion. These meetings are free and open to the public through the above listed toll-free number. Members of the public may join through the above listed toll-free number. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Carolyn Allen at *callen@usccr.gov.in* the Regional Program Unit Office/Advisory Committee Management Unit. Persons who desire additional information may contact the Regional Programs Unit Office at 202–539–8246.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzlBAAQ* under the Commission on Civil Rights, Kentucky Advisory Committee link. Persons interested in the work of this Committee are also directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit office at the above email or

Agenda

1. Opening
2. Panelist Presentations
3. Committee Q&A
4. Open Session
5. Next Steps/Other Business
6. Adjournment

Dated: July 24, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–16438 Filed 7–28–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Notice and opportunity for public comment.

SUMMARY: The Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of the firms contributed importantly to the total or partial separation of the firms' workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

SUPPLEMENTARY INFORMATION:

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[6/19/2020 through 7/21/2020]

Firm name	Firm address	Date accepted for investigation	Product(s)
Integrated Textile Solutions, Inc	865 Cleveland Avenue, Salem, VA 24153.	6/29/2020	The firm manufactures tarpaulins and tents.
Evans Tool & Die, Inc	157 North Salem Road NE, Conyers, GA 30013.	7/9/2020	The firm manufactures metal stamped parts.
Marc Manufacturing, Inc., d/b/a Qualtek Manufacturing, Inc.	4230 North Nevada Avenue, Colorado Springs, CO 80907.	7/21/2020	The firm manufactures miscellaneous fabricated metal parts.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Bryan Borlik,

Director.

[FR Doc. 2020–16406 Filed 7–28–20; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–525–001, A–351–854, A–891–001, A–729–803, A–428–849, A–484–804, A–533–895, A–560–835, A–475–842, A–580–906, A–523–814, A–485–809, A–801–001, A–856–001, A–791–825, A–469–820, A–583–867, A–489–839]

Common Alloy Aluminum Sheet From Bahrain, Brazil, Croatia, Egypt, Germany, Greece, India, Indonesia, Italy, Republic of Korea, Oman, Romania, Serbia, Slovenia, South Africa, Spain, Taiwan, and the Republic of Turkey: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable July 29, 2020.

FOR FURTHER INFORMATION CONTACT: Allison Hollander at (202) 482–2805 (Bahrain); Shanah Lee at (202) 482–6386 (Brazil); Irene Gorelik at (202) 482–6905 (Croatia); Magd Zalok at (202) 482–4162 (Egypt); Jonathan Hill at (202) 482–3518 (Germany); Samantha Kinney at (202) 482–2285 (Greece); Jasun Moy at (202) 482–8194 (India); John Drury at (202) 482–0195 and Glenn Bass at (202) 482–8338 (Indonesia); Kathryn Wallace at (202) 482–6251 (Italy); Matthew Renkey at (202) 482–2312 (Republic of Korea (Korea)); Chelsey Simonovich at (202) 482–1979 (Oman); Krisha Hill at (202) 482–4037 (Romania); Jaron Moore at (202) 482–3640 (Serbia); Faris Montgomery at (202) 482–1537 (Slovenia); Laurel LaCivita at (202) 482–4243 (South Africa); Rachel Greenberg at (202) 482–0652 (Spain); Kathryn Turlo at (202) 482–3870 (Taiwan); and Sean Carey at (202) 482–3964 (Republic of Turkey (Turkey)), AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On March 30, 2020, the Department of Commerce (Commerce) initiated less-than-fair-value (LTFV) investigations of imports of common alloy aluminum sheet (aluminum sheet) from Bahrain, Brazil, Croatia, Egypt, Germany, Greece, India, Indonesia, Italy, Korea, Oman, Romania, Serbia, Slovenia, South Africa, Spain, Taiwan, and Turkey.[1] Currently, the preliminary determinations are due no later than August 17, 2020.

Postponement of Preliminary Determinations

Section 733(b)(1)(A) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in an LTFV investigation within 140 days after the date on which Commerce initiated the investigation. However, section 733(c)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 190 days after the date on which Commerce initiated the investigation if: (A) The petitioner makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.

On July 16, 2020, the petitioners[2] submitted a timely request that Commerce postpone the preliminary determinations in these LTFV investigations.[3] The petitioners stated that they request postponement so that Commerce may review the petitioners' comments on the questionnaire responses, issue supplemental questionnaires, and conduct a complete

[1] *See Common Alloy Aluminum Sheet from Bahrain, Brazil, Croatia, Egypt, Germany, Greece, India, Indonesia, Italy, Republic of Korea, Oman, Romania, Serbia, Slovenia, South Africa, Spain, Taiwan and the Republic of Turkey: Initiation of Less-Than-Fair-Value Investigations,* 85 FR 19444 (April 7, 2020).

[2] The petitioners are the Aluminum Association Common Alloy Aluminum Sheet Trade Enforcement Working Group and its individual members: Aleris Rolled Products, Inc.; Arconic, Inc.; Constellium Rolled Products Ravenswood, LLC; JW Aluminum Company; Novelis Corporation; and Texarkana Aluminum, Inc.

[3] *See* Petitioners' Letter, ''Common Alloy Aluminum Sheet from Bahrain, Brazil, Croatia, Egypt, Germany, Greece, India, Indonesia, Italy, Republic of Korea, Oman, Romania, Serbia, Slovenia, South Africa, Spain, Taiwan and the Republic of Turkey,'' dated July 16, 2020.

and thorough analysis in these investigations.[4]

For the reasons stated above, and because there are no compelling reasons to deny the request, Commerce, in accordance with section 733(c)(1)(A) of the Act, is postponing the deadline for the preliminary determinations by 50 days (*i.e.,* 190 days after the date on which these investigations were initiated). As a result, Commerce will issue its preliminary determinations no later than October 6, 2020. In accordance with section 735(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determinations in these investigations will continue to be 75 days after the date of the preliminary determinations, unless postponed at a later date.

Notification to Interested Parties

This notice is issued and published pursuant to section 733(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: July 22, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–16427 Filed 7–28–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–943]

Certain Oil Country Tubular Goods From the People's Republic of China: Final Results of Expedited Second Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this sunset review, the Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on certain oil country tubular goods (OCTG) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable July 29, 2020.

FOR FURTHER INFORMATION CONTACT: Moses Song or Natasia Harrison, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Street and Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–7885 or (202) 482–1240, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2020, Commerce published a notice of initiation of the second sunset review of the AD order on OCTG from China, pursuant to section 751(c)(2) of the Tariff Act of 1930, as amended (the Act).[1] On April 14, 2020, and April 16, 2020, Commerce received notices of intent to participate in this review from Maverick Tube Corporation (Maverick), Tenaris Bay City, Inc. (Tenaris), IPSCO Tubulars, Inc. (IPSCO), BENTELER Steel/Tube Manufacturing Corp. (BENTELER), United States Steel Corporation (U.S. Steel), Welded Tube USA Inc. (Welded Tube), and Vallourec Star, L.P. (Vallourec) (collectively, domestic interested parties) within the deadline specified in 19 CFR 351.218(d)(1)(i).[2] The domestic interested parties claimed interested party status under section 771(9)(C) of the Act, as manufacturers of a domestic like product in the United States.

On May 1, 2020, Commerce received a complete substantive response from the domestic interested parties within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[3] We received no substantive responses from any respondent interested party, nor was a hearing requested. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the AD order on OCTG from China.

Scope of the Order

This AD order covers OCTG. The Issues and Decision Memorandum, which is hereby adopted by this notice, provides a full description of the scope of the order.[4]

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 Decision Memorandum can be accessed at *http://enforcement.trade.gov/frn/.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Analysis of Comments Received

In the Issues and Decision Memorandum, we have addressed all issues that parties raised in this review. The issues include the likelihood of continuation or recurrence of dumping in the event of revocation and the magnitude of the dumping margins likely to prevail if Commerce revoked the AD order.

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(c)(3) of the Act, we determine that revocation of the AD order on OCTG from China would be likely to lead to continuation or recurrence of dumping, and that the magnitude of the margins of dumping likely to prevail would be up to 99.14 percent.

Notification to Interested Parties

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction. We are issuing and publishing these results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218.

[1] *See Initiation of Five-Year (Sunset) Reviews,* 85 FR 18189 (April 1, 2020).

[2] *See* Maverick, Tenaris, and IPSCO's Letter, ''Notice of Intent to Participate in Second Sunset Reviews of the Antidumping and Countervailing Duty Orders on Oil Country Tubular Goods from the People's Republic of China,'' dated April 14, 2020; *see also* U.S. Steel's Letter, ''Five-Year (''Sunset'') Review of Antidumping and Countervailing Duty Orders on Oil Country Tubular Goods from China: Notice of Intent to Participate,'' dated April 16, 2020; Vallourec and Welded Tube's Letter, ''Oil Country Tubular Goods from the People's Republic of China, Second Sunset Review: Notice of Intent to Participate,'' dated April 16, 2020; and BENTELER's Letter, ''Notice of Intent to Participate in Second Sunset Reviews of the Antidumping and Countervailing Duty Orders on Oil Country Tubular Goods from the People's Republic of China,'' dated April 16, 2020.

[3] *See* Domestic Interested Parties' Letter, ''Oil Country Tubular Goods from the People's Republic of China: Substantive Response of the Domestic Industry to Commerce's Notice of Initiation of Five-Year (''Sunset'') Reviews,'' dated May 1, 2020.

[4] *Id.*

[4] *See* Memorandum, ''Expedited Second Sunset Review of the Antidumping Duty Order on Certain Oil Country Tubular Goods from the People's Republic of China: Issues and Decision Memorandum,'' dated concurrently with this notice (Issues and Decision Memorandum).

Dated: July 22, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2020–16426 Filed 7–28–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA240]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Site Characterization Surveys Off the Coast of Massachusetts

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to Mayflower Wind Energy LLC (Mayflower) to incidentally harass, by Level B harassment only, marine mammals during site characterization surveys off the coast of Massachusetts in the area of the Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf (OCS–A 0521) and along a potential submarine cable route to landfall at Falmouth, Massachusetts.

DATES: This authorization is effective from July 23, 2020 to July 22, 2021.

FOR FURTHER INFORMATION CONTACT: Amy Fowler, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed incidental take authorization may be provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth.

Summary of Request

On January 17, 2020, NMFS received a request from Mayflower for an IHA to take marine mammals incidental to site characterization surveys in the area of the Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf (OCS–A 0521; Lease Area) and a submarine export cable route connecting the Lease Area to landfall in Falmouth, Massachusetts. A revised application was received on April 9, 2020. NMFS deemed that request to be adequate and complete. Mayflower's request is for take of a small number of 14 species of marine mammals by Level B harassment only. Neither Mayflower nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of the Specified Activity

Mayflower plans to conduct marine site characterization surveys, including high-resolution geophysical (HRG) and geotechnical surveys, in the area of Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf #OCS–A 0521 (Lease Area), located approximately 60 kilometers (km) south of Martha's Vineyard, Massachusetts, and along a potential submarine cable route to landfall at Falmouth, Massachusetts.

The purpose of the planned surveys is to acquire geotechnical and HRG data on the bathymetry, seafloor morphology, subsurface geology, environmental/biological sites, seafloor obstructions, soil conditions, and locations of any man-made, historical, or archaeological resources within the Lease Area and export cable route to support development of offshore wind energy facilities. Up to three survey vessels may operate concurrently as part of the surveys, but the three vessels will spend no more than a combined total of 215 days at sea. Surveys are expected to occur over a three-month period, beginning upon issuance of the IHA. Underwater sound resulting from Mayflower's site characterization surveys has the potential to result in incidental take of marine mammals in the form of behavioral harassment.

The HRG survey activities planned by Mayflower are described in detail in the notice of proposed IHA (85 FR 31856; May 27, 2020). The HRG equipment planned for use is shown in Table 1.

TABLE 1—SUMMARY OF HRG SURVEY EQUIPMENT PLANNED FOR USE BY MAYFLOWER

HRG equipment category	Specific HRG equipment	Operating frequency range (kHz)	Source level (dB rms)	Beamwidth (degrees)	Typical pulse duration (ms)	Pulse repetition rate (Hz)
Sparker	Geomarine Geo-Spark 800 J system.	0.25 to 5	203	180	3.4	2

TABLE 1—SUMMARY OF HRG SURVEY EQUIPMENT PLANNED FOR USE BY MAYFLOWER—Continued

HRG equipment category	Specific HRG equipment	Operating frequency range (kHz)	Source level (dB rms)	Beamwidth (degrees)	Typical pulse duration (ms)	Pulse repetition rate (Hz)
Sub-bottom profiler.	Edgetech 3100 with SB–2–16S towfish.	2 to 16	179	65	10	10
	Innomar SES–2000 Medium-100 Parametric.	85 to 115	241	2	2	40

As described above, a detailed description of the planned HRG surveys is provided in the **Federal Register** notice for the proposed IHA (85 FR 31856; May 27, 2020). Since that time, no changes have been made to the planned HRG survey activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specific activity. Mitigation, monitoring, and reporting measures are described in detail later in this document (please see Mitigation and Monitoring and Reporting below).

Comments and Responses

A notice of NMFS's proposal to issue an IHA to Mayflower was published in the **Federal Register** on May 27, 2020 (85 FR 31856). That notice described, in detail, Mayflower's activity, the marine mammal species that may be affected by the activity, and the anticipated effects on marine mammals. During the 30-day public comment period, NMFS received comment letters from the Marine Mammal Commission (Commission) and a group of environmental non-governmental organizations (ENGOs) including the Natural Resources Defense Council, National Wildlife Foundation, Conservation Law Foundation, Whale and Dolphin Conservation North America, Defenders of Wildlife, Humane Society of the United States, Humane Society Legislative Fund, International Fund for Animal Welfare, Mass Audubon, Marine Mammal Alliance Nantucket, NY4WHALES, Surfrider Foundation, Friends of the Earth, Ocean Conservation Research, and Sanctuary Education Advisory Specialists. NMFS has posted the comments online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable.* A summary of the public comments received from the Commission and ENGOs as well as NMFS' responses to those comments are below.

Comment 1: The Commission recommends that NMFS (1) prohibit Mayflower and other action proponents from using the impulsive Level A harassment thresholds for estimating the extents of the Level A harassment zones for non-impulsive sources (*i.e.,* echosounders, shallow-penetration sub-bottom profilers (SBPs), pingers, etc.) and (2) require action proponents to use the correct Level A harassment thresholds in all future applications. The Commission further recommends that NMFS justify why it is allowing action proponents to characterize sources in a manner inconsistent with its own acoustic guidance (NMFS 2018).

Response: NMFS concurs with the Commission's recommendations and will work to ensure that applicants are using the correct harassment thresholds in all future applications. As described in the notice of proposed IHA, NMFS does not agree with Mayflower's characterization of certain HRG sources as impulsive sources. However, this characterization results in more conservative modeling results and take estimates than if the Level A harassment thresholds for non-pulse sources were used and in this case, no Level A harassment is predicted or authorized.

Comment 2: The Commission recommends that NMFS use its revised user spreadsheet, in-beam source levels, the actual beamwidth proposed to be used, and the maximum water depth in the survey area to estimate the Level B harassment zones for Mayflower's activities and all future proposed authorizations involving HRG sources.

Response: NMFS' interim guidance for determining Level B harassment zones from HRG sources does incorporate operating frequency and beam width. We strongly recommend that applicants employ these tools, as we believe they are generally the best methodologies that are currently available. However, applicants are free to develop additional models or use different tools if they believe they are more representative of real-world conditions. NMFS will evaluate those tools and either use them where appropriate, or recommend changes. In this case, we note that the Level B harassment zones calculated by Mayflower using JASCO's model are the same as those calculated using NMFS's interim guidance with the exception of the Innomar parametric SBP, for which JASCO's model calculates a more conservative Level B harassment zone by incorporating out-of-beam sound levels.

Comment 3: To maximize efficiencies and ensure best available science is being used, the Commission recommends that NMFS consult with its acoustic experts to determine how to estimate Level A harassment zones accurately, what Level A harassment zones are actually expected, and whether it is necessary to estimate Level A harassment zones for HRG surveys in general.

Response: NMFS agrees with the Commission's recommendation and is working with our acoustic experts to evaluate the appropriate methods for determining the potential for Level A harassment from HRG surveys.

Comment 4: The Commission recommends that NMFS and BOEM expedite efforts to develop and finalize, in the next six months, methodological and signal processing standards for HRG sources. Those standards should be used by action proponents that conduct HRG surveys and that either choose to conduct in-situ measurements to inform an authorization application or are required to conduct measurements to fulfill a lease condition set forth by BOEM.

Response: NMFS agrees with the Commission that methodological and signal processing standards for HRG sources is warranted and is working on developing such standards. However, the effort is resource-dependent and NMFS cannot ensure such standards will be developed within the Commission's preferred time frame.

Comment 5: The Commission recommends that NMFS evaluate the impacts of sound sources consistently across all action proponents and deem sources *de minimis* in a consistent manner for all proposed incidental harassment authorizations and rulemakings. This has the potential to reduce burdens on both action proponents and NMFS.

Response: NMFS concurs with the Commission's recommendation and is currently working together with BOEM to develop a tool to assist applicants and NMFS in more quickly and efficiently identifying activities and mitigation approaches that are unlikely to result in take of marine mammals.

Comment 6: The Commission recommends that NMFS consider whether, in such situations involving HRG surveys, incidental harassment authorizations are necessary given the small size of the Level B harassment zones, the proposed shutdown requirements, and the added protection afforded by the lease-stipulated exclusion zones. Specifically, the Commission states that NMFS should evaluate whether taking needs to be authorized for those sources that are not considered *de minimis,* including sparkers and boomers, and for which implementation of the various mitigation measures should be sufficient to avoid Level B harassment takes.

Response: NMFS has evaluated whether taking needs to be authorized for those sources that are not considered *de minimis,* including sparkers and boomers, factoring into consideration the effectiveness of mitigation and monitoring measures, and we have determined that implementation of mitigation and monitoring measures cannot ensure that all take can be avoided during all HRG survey activities under all circumstances at this time. If and when we are able to reach such a conclusion, we will re-evaluate our determination that incidental take authorization is warranted for these activities.

Comment 7: The Commission recommends that NMFS require Mayflower to report as soon as possible and cease project activities immediately in the event of an unauthorized injury or mortality of a marine mammal from a vessel strike until the NMFS Office of Protected Resources and the NMFS New England/Mid-Atlantic Regional Stranding Coordinator determine whether additional measures are necessary to minimize the potential for additional unauthorized takes.

Response: NMFS has imposed a suite of measures in this IHA to reduce the risk of vessel strikes and does not anticipate, and has not authorized, any takes associated with vessel strikes. Further, in the event of a ship strike Mayflower is required both to collect and report an extensive suite of information that NMFS has identified in order to evaluate the ship strike, and to notify OPR and the New England/Mid-Atlantic Regional Stranding Coordinator as soon as feasible. At that point, as the Commission suggests, NMFS would work with the applicant to determine whether there are additional mitigation measures or modifications that could further reduce the likelihood of vessel strike for the activities. However, given the existing requirements and the very low likelihood of a vessel strike occurring, the protective value of ceasing operations while NMFS and Mayflower discuss potential additional mitigations in order to avoid a second highly unlikely event during that limited period is unclear, while a requirement for project activities to cease would not be practicable for a vessel that is operating on the open water. Therefore, NMFS does not concur that the measure is warranted and we have not included this requirement in the authorization. NMFS retains authority to modify the IHA and cease all activities immediately based on a vessel strike and will exercise that authority if warranted.

Comment 8: The Commission recommends that NMFS specify that IHA Renewals are a one-time opportunity in all **Federal Register** notices requesting comments on the possibility of an IHA Renewal and in all associated proposed and final IHAs.

Response: NMFS concurs and has specified this in the final IHA for Mayflower's activities and will include this in all future **Federal Register** notices and proposed and final authorizations.

Comment 9: The Commission recommends that NMFS refrain from issuing renewals for any authorization and instead use its abbreviated **Federal Register** notice process as that process is similarly expeditious and fulfills NMFS's intent to maximize efficiencies.

Response: NMFS does not agree with the Commission and, therefore, does not adopt the Commission's recommendations. NMFS believes IHA renewals can be appropriate in certain limited circumstances, which are described in the conditions for the IHA. NMFS has previously provided responses to this recommendation in multiple notices, including 84 FR 52464 (October 02, 2019), and will provide a more detailed response within 120 days, as required by section 202(d) of the MMPA.

Comment 10: The ENGOs recommended a seasonal restriction on site assessment and characterization activities in the Project Areas with the potential to harass North Atlantic right whales (*Eubalaena glacialis*) between January 1 and April 30, 2021.

Response: In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, we carefully consider two primary factors: (1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat; and (2) the practicability of the measures for applicant implementation, which may consider such things as relative cost and impact on operations.

NMFS is concerned about the status of the North Atlantic right whale population given that an unusual mortality event (UME) has been in effect for this species since June of 2017 and that there have been a number of recent mortalities. While the ensonified areas contemplated for any single HRG vessel are comparatively small and the anticipated resulting effects of exposure relatively lower-level, the potential impacts of multiple HRG vessels (up to three vessels are planned for use by Mayflower) operating simultaneously in areas of higher right whale density are not well-documented and warrant caution. However, Mayflower does not plan to conduct HRG survey operations during the timeframe suggested by the ENGOs, and their BOEM-approved survey plan requires surveys to end in September 2020. If Mayflower requests future authorizations that include HRG survey operations between January 1 and April 30, NMFS will consider the possibility of including seasonal restrictions.

Comment 11: The ENGOs recommended a prohibition on the commencement of geophysical surveys at night or during times of poor visibility. They stated that ramp up should occur during daylight hours only, to maximize the probability that North Atlantic right whales are detected and confirmed clear of the exclusion zone.

Response: We acknowledge the limitations inherent in detection of marine mammals at night. However, no injury is expected to result even in the absence of mitigation, given the very small estimated Level A harassment zones. Any potential impacts to marine mammals authorized for take would be limited to short-term behavioral responses. Restricting surveys in the manner suggested by the commenters may reduce marine mammal exposures by some degree in the short term, but would not result in any significant reduction in either intensity or duration of noise exposure. Vessels would also potentially be on the water for an extended time introducing noise into the marine environment. The restrictions recommended by the

commenters could result in the surveys spending increased time on the water, which may result in greater overall exposure to sound for marine mammals and increase the risk of a vessel strike; thus the commenters have not demonstrated that such a requirement would result in a net benefit. Furthermore, restricting the applicant to ramp-up only during daylight hours would have the potential to result in lengthy shutdowns of the survey equipment, which could result in the applicant failing to collect the data they have determined is necessary and, subsequently, the need to conduct additional surveys the following year. This would result in significantly increased costs incurred by the applicant. Thus, the restriction suggested by the commenters would not be practicable for the applicant to implement. In consideration of potential effectiveness of the recommended measure and its practicability for the applicant, NMFS has determined that restricting survey start-ups to daylight hours when visibility is unimpeded is not warranted or practicable in this case.

Comment 12: The ENGOs recommended that NMFS require monitoring an exclusion zone (EZ) for North Atlantic right whales of 1,000 meters (m), around each vessel conducting activities with noise levels that could result in injury or harassment to this species.

Response: Regarding the recommendation for a 1,000 m EZ specifically for North Atlantic right whales, we have determined that the 500-m EZ, as required in the IHA, is sufficiently protective. We note that the 500-m EZ exceeds the modeled distance to the largest Level B harassment isopleth distance (141 m) by a substantial margin. Thus, we are not requiring shutdown if a right whale is observed beyond 500-m.

Comment 13: The ENGOs recommended that a minimum of four PSOs should be required, following a two-on/two-off rotation, each responsible for scanning no more than 180° of the exclusion zone at any given time.

Response: NMFS does not agree with the commenters that a minimum of four PSOs should be required, following a two-on/two-off rotation, to meet the MMPA requirement that mitigation must effect the least practicable adverse impact upon the affected species or stocks and their habitat. Previous IHAs issued for HRG surveys have required that a single PSO must be stationed at the highest vantage point and engaged in general 360-degree scanning during daylight hours. The monitoring reports submitted to NMFS have demonstrated that the PSOs are able to detect marine mammals and implement appropriate mitigation measures, and project proponents have not exceeded take limits or reported unauthorized taking.

Comment 14: The ENGOs recommended that a combination of visual monitoring by PSOs and passive acoustic monitoring (PAM) should be used at all times that survey work is underway at noise levels that could injure or harm North Atlantic right whales.

Response: There are several reasons why we do not agree that use of PAM is warranted for 24-hour HRG surveys such as the one planned by Mayflower. While NMFS agrees that PAM can be an important tool for augmenting detection capabilities in certain circumstances, its utility in further reducing impact for Mayflower's planned HRG survey activities is limited. First, for this activity, the area expected to be ensonified above the Level B harassment threshold is relatively small (a maximum of 141 m as described in the *Estimated Take* section)—this reflects the fact that, to start with, the source level is comparatively low and the intensity of any resulting impacts would be lower level and, further, it means that inasmuch as PAM will only detect a portion of any animals exposed within a zone (see below), the overall probability of PAM detecting an animal in the harassment zone is low—together these factors support the limited value of PAM for use in reducing take with smaller zones. PAM is only capable of detecting animals that are actively vocalizing, while many marine mammal species vocalize infrequently or during certain activities, which means that only a subset of the animals within the range of the PAM would be detected (and potentially have reduced impacts). Additionally, localization and range detection can be challenging under certain scenarios. For example, odontocetes are fast moving and often travel in large or dispersed groups which makes localization difficult. In addition, the ability of PAM to detect baleen whale vocalizations is further limited due to being deployed from the stern of a vessel, which puts the PAM hydrophones in proximity to propeller noise and low frequency engine noise which can mask the low frequency sounds emitted by baleen whales, including right whales.

We also note that the effects to North Atlantic right whales, and all marine mammals, from the types of surveys authorized in this IHA are expected to be limited to low level behavioral harassment even in the absence of mitigation; no injury is expected or authorized. In consideration of the limited additional benefit anticipated by adding this detection method (especially for right whales and other low frequency cetaceans, species for which PAM has limited efficacy) and the cost and impracticability of implementing a full-time PAM program, we have determined the current requirements for visual monitoring are sufficient to ensure the least practicable adverse impact on the affected species or stocks and their habitat. However, we note that Mayflower will voluntarily implement PAM during night operations as an added precautionary measure even though this is not a NMFS requirement.

Comment 15: The ENGOs recommended that NMFS require developers to select SBP systems and operate those systems at power settings that achieve the lowest practicable source level for the objective.

Response: Mayflower has selected the equipment necessary to achieve their objectives. We have evaluated the sound produced by their equipment, and made the necessary findings to authorize taking of marine mammals incidental to Mayflower's survey activities.

Comment 16: The ENGOs recommended a requirement that all project vessels (regardless of size) operating within the Project Area observe a mandatory 10 knot speed restriction during the entire survey period. The commenters also recommend that if survey activities are delayed into the fall and winter, all project vessels either transiting to/from or operating within the Project Area must observe a 10 knot (18.5 kilometer (km)/hour) speed restriction between November 1, 2020 and April 30, 2021.

Response: NMFS has analyzed the potential for ship strike resulting from Mayflower's activity and has determined that the mitigation measures specific to ship strike avoidance are sufficient to avoid the potential for ship strike. These include: A requirement that all vessel operators comply with 10 knot (18.5 km/hour) or less speed restrictions in any established dynamic management area (DMA); a requirement that all vessel operators reduce vessel speed to 10 knots (18.5 km/hour) or less when any large whale, any mother/calf pairs, pods, or large assemblages of non-delphinoid cetaceans are observed within 100 m of an underway vessel; a requirement that all survey vessels maintain a separation distance of 500-m or greater from any sighted North Atlantic right whale; a requirement that, if underway, vessels must steer a course

away from any sighted North Atlantic right whale at 10 knots or less until the 500-m minimum separation distance has been established; and a requirement that, if a North Atlantic right whale is sighted in a vessel's path, or within 500 m of an underway vessel, the underway vessel must reduce speed and shift the engine to neutral. We have determined that the ship strike avoidance measures are sufficient to ensure the least practicable adverse impact on species or stocks and their habitat. As noted previously, occurrence of vessel strike during surveys is extremely unlikely based on the low vessel speed of approximately 3 knots (5.6 km/hour) while transiting survey lines. Furthermore, no documented vessel strikes have occurred for any HRG surveys which were issued IHAs from NMFS.

Comment 17: The ENGOs objected to NMFS' process to consider extending any one-year IHA with a truncated 15-day comment period as contrary to the MMPA.

Response: NMFS' IHA Renewal process meets all statutory requirements. All IHAs issued, whether an initial IHA or a Renewal IHA, are valid for a period of not more than one year. In addition, the public has at least 30 days to comment on all proposed IHAs, with a cumulative total of 45 days for IHA Renewals. As noted above, the *Request for Public Comments* section made clear that the agency was seeking comment on both the initial proposed IHA and the potential issuance of a Renewal for this project. Because any Renewal (as explained in the *Request for Public Comments* section) is limited to another year of identical or nearly identical activities in the same location (as described in the *Description of Proposed Activity* section) or the same activities that were not completed within the one-year period of the initial IHA, reviewers have the information needed to effectively comment on both the immediate proposed IHA and a possible one-year Renewal, should the IHA holder choose to request one in the coming months.

While there will be additional documents submitted with a Renewal request, for a qualifying Renewal these will be limited to documentation that NMFS will make available and use to verify that the activities are identical to those in the initial IHA, are nearly identical such that the changes would have either no effect on impacts to marine mammals or decrease those impacts, or are a subset of activities already analyzed and authorized but not completed under the initial IHA. NMFS will also confirm, among other things, that the activities will occur in the same location; involve the same species and stocks; provide for continuation of the same mitigation, monitoring, and reporting requirements; and that no new information has been received that would alter the prior analysis. The Renewal request will also contain a preliminary monitoring report, but that is to verify that effects from the activities do not indicate impacts of a scale or nature not previously analyzed. The additional 15-day public comment period provides the public an opportunity to review these few documents, provide any additional pertinent information and comment on whether they think the criteria for a Renewal have been met. Between the initial 30-day comment period on these same activities and the additional 15 days, the total comment period for a Renewal is 45 days.

In addition to the IHA Renewal process being consistent with all requirements under section 101(a)(5)(D), it is also consistent with Congress' intent for issuance of IHAs to the extent reflected in statements in the legislative history of the MMPA. Through the provision for Renewals in the regulations, description of the process and express invitation to comment on specific potential Renewals in the Request for Public Comments section of each proposed IHA, the description of the process on NMFS' website, further elaboration on the process through responses to comments such as these, posting of substantive documents on the agency's website, and provision of 30 or 45 days for public review and comment on all proposed initial IHAs and Renewals respectively, NMFS has ensured that the public ''is invited and encouraged to participate fully in the agency decision-making process.''

Comment 18: The ENGOs suggested that it should be NMFS' top priority to consider any initial data from state monitoring efforts, passive acoustic monitoring data, opportunistic marine mammal sightings data, satellite telemetry, and other data sources, because the models used by NMFS do not adequately capture increased use of the survey areas by right whales. Further, these commenters state that the density models NMFS uses result in an underestimate of take, and NMFS should take steps now to develop a dataset that more accurately reflects marine mammal presence so that it is in hand for future IHA authorizations and other work.

Response: NMFS will review any recommended data sources and will continue to use the best available information. We welcome future input from interested parties on data sources that may be of use in analyzing the potential presence and movement patterns of marine mammals, including North Atlantic right whales, in New England waters. NMFS will review any recommended data sources and will continue to use the best available information. NMFS has used the best available scientific information—in this case the marine mammal density models developed by the Duke Marine Geospatial Ecology Lab (MGEL) (Roberts et al. 2016, 2017, 2018)—to inform our determinations. While the ENGOs are correct in their statement that North Atlantic right whale distribution has shifted in recent years and sightings databases, passive acoustic monitoring, and satellite telemetry data may provide additional information on right whale presence in the Project Area, no references were provided to support any change in density estimates or estimated take for North Atlantic right whales. Therefore, NMFS has not made any changes to the density information or estimated take presented in the **Federal Register** notice of proposed IHA.

Comment 19: The ENGOs commented that NMFS should analyze the cumulative impacts from Mayflower's survey activities, and other survey activities, on North Atlantic right whales and other protected species.

Response: The MMPA grants exceptions to its broad take prohibition for a ''specified activity.'' 16 U.S.C. 1371(a)(5)(A)(i). Cumulative impacts (also referred to as cumulative effects) is a term that appears in the context of NEPA and the ESA, but it is defined differently in those contexts. Neither the MMPA nor NMFS' codified implementing regulations address consideration of other unrelated activities and their impacts on populations. However, the preamble for NMFS' implementing regulations (54 FR 40338; September 29, 1989) states in response to comments that the impacts from other past and ongoing anthropogenic activities are to be incorporated into the negligible impact analysis via their impacts on the baseline. Accordingly, NMFS here has factored into its negligible impact analyses the impacts of other past and ongoing anthropogenic activities via their impacts on the baseline (*e.g.,* as reflected in the density/distribution and status of the species, population size and growth rate, and other relevant stressors).

Changes From the Proposed IHA to Final IHA

The estimated take in the proposed IHA was based on monthly density

estimates and the expected months of survey operations (June through September). The survey timing has shifted and surveys are now expected to occur from July through September. Mayflower plans to conduct the same number of survey days, but rather than averaging the survey duration over four months, it has been averaged over three months. Estimated take has been recalculated by excluding density estimates for the month of June. By shifting the expected survey effort in June to the July-September period, the estimated takes for most species either decreased or remained the same. This is because the expected June densities of most species are higher than densities during the July-September period. However, for bottlenose dolphins (*Tursiops truncatus*) and common dolphins (*Delphinus delphis*), the densities during July-September are somewhat higher than those during June, so the take estimates for those two species increased. For bottlenose dolphins, the estimated take by Level B harassment increased from 739 to 812 and for common dolphins, the estimated take by Level B harassment increased from 278 to 318. As a conservative approach, NMFS has authorized the higher estimated take from these two calculations.

In the proposed IHA, NMFS included an exclusion zone of 100-m for all marine mammal species other than North Atlantic right whales, which required a 500-m exclusion zone, and certain genera of dolphins (*Delphinus, Lagenorhynchus,* and *Tursiops*) that are most likely to voluntarily approach the source vessel for purposes of interacting with the vessel (*e.g.,* bow riding). We included this small dolphin exception because shutdown requirements for small dolphins represent practicability concerns without likely commensurate benefits for the animals in question. Small dolphins are typically the most commonly observed marine mammals in the specific geographic region and would typically be the only marine mammals likely to intentionally approach the vessel. However, since the proposed IHA was published in the **Federal Register** on May 27, 2020 (85 FR 31856), Mayflower has been conducting geotechnical surveys in the Project Area and has reported numerous gray seals (*Halichoerus grypus*) and harbor seals (*Phoca vitulina*) voluntarily approaching the vessels, within 100 m. Mayflower expects that similar conditions may occur during the planned HRG surveys, which would result in additional shutdowns. The potential for increased shutdowns resulting from pinnipeds approaching within 100 m would require the survey vessel to revisit the missed track line to reacquire data, resulting in an overall increase in the total sound energy input to the marine environment and an increase in the total duration over which the survey is active in a given area. Removing the 100-m exclusion zone for pinnipeds would reduce the operational burden on Mayflower, and as described below in the *Estimated Take* section, even absent mitigation, NMFS does not expect that auditory injury is likely to occur to any marine mammal species. NMFS concurs that there is no meaningful benefit to retaining the 100-m exclusion zone for pinnipeds, and has changed the mitigation requirements to include pinnipeds in the shutdown exemption for animals that intentionally approach the vessel. Pinnipeds that enter the Level B harassment zone will be recorded as Level B takes. No changes have been made to the number of seals expected to be taken by Level B harassment.

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SARs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS's website. (*https://www.fisheries.noaa.gov/find-species*).

Table 2 lists all species or stocks for which take is expected and authorized for this action, and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2019). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS's SARs). While no mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS's U.S. Atlantic SARs. All values presented in Table 2 are the most recent available at the time of publication and are available in the 2018 Atlantic and Gulf of Mexico Marine Mammal Stock Assessments (Hayes *et al.,* 2019a), available online at*: www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region* or and draft 2019 Atlantic and Gulf of Mexico Marine Mammal Stock Assessments (Hayes *et al.* 2019b) available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports.*

TABLE 2—MARINE MAMMALS KNOWN TO OCCUR IN THE PROJECT AREA THAT MAY BE AFFECTED BY MAYFLOWER'S PLANNED ACTIVITY

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	Predicted abundance [3]	PBR [4]	Annual M/SI [4]
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)							
Family Balaenidae:							
North Atlantic right whale	*Eubalaena glacialis*	Western North Atlantic.	E/D; Y	428 (0; 418; n/a)	*535 (0.45)	0.9	5.56

TABLE 2—MARINE MAMMALS KNOWN TO OCCUR IN THE PROJECT AREA THAT MAY BE AFFECTED BY MAYFLOWER'S PLANNED ACTIVITY—Continued

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	Predicted abundance [3]	PBR [4]	Annual M/SI [4]
Family Balaenopteridae (rorquals):							
Humpback whale	*Megaptera novaeangliae*	Gulf of Maine	-/-; N	1,396 (0; 1,380; See SAR)	*1,637 (0.07)	22	12.15
Fin whale	*Balaenoptera physalus*	Western North Atlantic.	E/D; Y	7,418 (0.25; 6,029; See SAR).	4,633 (0.08)	12	2.35
Sei whale	*Balaenoptera borealis*	Nova Scotia	E/D; Y	6292 (1.015; 3,098; see SAR)236.	*717 (0.30)	6.2	1
Minke whale	*Balaenoptera acutorostrata*	Canadian East Coast.	-/-; N	24,202 (0.3; 18,902; See SAR).	*2,112 (0.05)	1,189	8
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)							
Family Physeteridae:							
Sperm whale	*Physeter macrocephalus*	NA	E; Y	4349 (0.28;3,451; See SAR)	5,353 (0.12)	6.9	0
Family Delphinidae:							
Long-finned pilot whale	*Globicephala melas*	Western North Atlantic.	-/-; Y	5,636 (0.63; 3,464)	[5] 18,977 (0.11)	35	38
Bottlenose dolphin	*Tursiops spp*	Western North Atlantic Offshore.	-/-; N	62,851 (0.23; 51,914; See SAR).	[5] 97,476 (0.06)	591	28
Common dolphin	*Delphinus delphis*	Western North Atlantic.	-/-; N	172,825 (0.21; 145,216; See SAR).	86,098 (0.12)	1,452	419
Atlantic white-sided dolphin.	*Lagenorhynchus acutus*	Western North Atlantic.	-/-; N	92,233 (0.71; 54,433; See SAR).	37,180 (0.07)	544	26
Risso's dolphin	*Grampus griseus*	Western North Atlantic.	-/-; N	35,493 (0.19; 30,289; See SAR).	7,732 (0.09)	303	54.3
Family Phocoenidae (porpoises):							
Harbor porpoise	*Phocoena phocoena*	Gulf of Maine/Bay of Fundy.	-/-; N	95,543 (0.31; 74,034; See SAR).	*45,089 (0.12)	851	217
Order Carnivora—Superfamily Pinnipedia							
Family Phocidae (earless seals):							
Gray seal [6]	*Halichoerus grypus*	Western North Atlantic.	-/-; N	27,131 (0.19; 23,158, 2016)	N/A	1,389	5,688
Harbor seal	*Phoca vitulina*	Western North Atlantic.	-/-; N	75,834 (0.15; 66,884, 2018)	N/A	345	333

1—Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

2—NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region/*. CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable

3—This information represents species- or guild-specific abundance predicted by recent habitat-based cetacean density models (Roberts *et al.,* 2016, 2017, 2018). These models provide the best available scientific information regarding predicted density patterns of cetaceans in the U.S. Atlantic Ocean, and we provide the corresponding abundance predictions as a point of reference. Total abundance estimates were produced by computing the mean density of all pixels in the modeled area and multiplying by its area. For those species marked with an asterisk, the available information supported development of either two or four seasonal models; each model has an associated abundance prediction. Here, we report the maximum predicted abundance.

4—Potential biological removal, defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population size (OSP). Annual M/SI, found in NMFS' SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, subsistence hunting, ship strike). Annual M/SI values often cannot be determined precisely and is in some cases presented as a minimum value. All M/SI values are as presented in the draft 2019 SARs (Hayes *et al.,* 2019).

5—Abundance estimates are in some cases reported for a guild or group of species when those species are difficult to differentiate at sea. Similarly, the habitat-based cetacean density models produced by Roberts *et al.* (2016, 2017, 2018) are based in part on available observational data which, in some cases, is limited to genus or guild in terms of taxonomic definition. Roberts *et al.* (2016, 2017, 2018) produced density models to genus level for *Globicephala* spp. and produced a density model for bottlenose dolphins that does not differentiate between offshore and coastal stocks.

6—8 NMFS stock abundance estimate applies to U.S. population only, actual stock abundance is approximately 505,000.

As indicated above, all 14 species (with 14 managed stocks) in Table 2 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur, and we have authorized it. All species that could potentially occur in the planned survey areas are included in Table 4 of the IHA application. However, the temporal and/or spatial occurrence of several species listed in Table 4 in the IHA application is such that take of these species is not expected to occur. The blue whale (*Balaenoptera musculus*), Cuvier's beaked whale (*Ziphius cavirostris*), four species of Mesoplodont beaked whale (*Mesoplodon* spp.), dwarf and pygmy sperm whale (*Kogia sima* and *Kogia breviceps*), and striped dolphin (*Stenella coeruleoalba*), typically occur further offshore than the Project Area, while short-finned pilot whales (*Globicephala macrorhynchus*) and Atlantic spotted dolphins (*Stenella frontalis*) are typically found further south than the Project Area (Hayes *et al.,* 2019b). There are stranding records of harp seals (*Pagophilus groenlandicus*) in Massachusetts, but the species typically occurs north of the Project Area and appearances in Massachusetts usually occur between January and May, outside of the planned survey dates (Hayes *et al.,* 2019b). As take of these species is not anticipated as a result of the planned activities, these species are not analyzed further.

A detailed description of the species for which take has been authorized,

including brief introductions to the relevant stocks as well as available information regarding population trends and threats, and information regarding local occurrence, were provided in the **Federal Register** notice for the proposed IHA (85 FR 31856; May 27, 2020); since that time, we are not aware of any changes in the status of these species and stocks; therefore, detailed descriptions are not provided here. Please refer to that **Federal Register** notice for these descriptions. Please also refer to NMFS' website (*https://www.fisheries.noaa.gov/find-species*) for generalized species accounts.

Potential Effects of Specified Activities on Marine Mammals and their Habitat

The effects of underwater noise from Mayflower's survey activities have the potential to result in take of marine mammals by harassment in the vicinity of the survey area. The **Federal Register** notice for the proposed IHA (85 FR 31856; May 27, 2020) included a discussion of the effects of anthropogenic noise on marine mammals and their habitat. That information and analysis is incorporated by reference into this final IHA determination and is not repeated here; please refer to the notice of proposed IHA (85 FR 31856; May 27, 2020).

Estimated Take

This section provides an estimate of the number of incidental takes authorized through this IHA, which will inform both NMFS' consideration of ''small numbers'' and the negligible impact determination.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would be by Level B harassment only in the form of disruption of behavioral patterns for individual marine mammals resulting from exposure to HRG sources. Based on the nature of the activity and the anticipated effectiveness of the mitigation measures (*i.e.,* exclusion zones and shutdown measures), discussed in detail below in the *Mitigation* section, Level A harassment is neither anticipated nor authorized.

As described previously, no mortality is anticipated or authorized for this activity. Below we describe how the take is estimated.

Generally speaking, we estimate take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) and the number of days of activities. We note that while these basic factors can contribute to a basic calculation to provide an initial prediction of takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the authorized take.

Acoustic Thresholds

Using the best available science, NMFS has developed acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur permanent threshold shift (PTS) of some degree (equated to Level A harassment).

Level B Harassment for non-explosive sources—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source (*e.g.,* frequency, predictability, duty cycle), the environment (*e.g.,* bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.,* 2007, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS predicts that marine mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 160 decibels (dB) re 1 microPascal (μPa) (root mean square (rms)) for impulsive and/or intermittent sources (*e.g.,* impact pile driving) and 120 dB rms for continuous sources (*e.g.,* vibratory driving). Mayflower's planned activity includes the use of impulsive sources (geophysical survey equipment), and therefore use of the 160 dB re 1 μPa (rms) threshold is applicable.

Level A harassment for non-explosive sources—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). The components of Mayflower's planned activity includes the use of impulsive sources.

Predicted distances to Level A harassment isopleths, which vary based on marine mammal functional hearing groups were calculated. The updated acoustic thresholds for impulsive sounds (such as HRG survey equipment) contained in the Technical Guidance (NMFS, 2018) were presented as dual metric acoustic thresholds using both cumulative sound exposure level (SEL_{cum}) and peak sound pressure level metrics. As dual metrics, NMFS considers onset of PTS (Level A harassment) to have occurred when either one of the two metrics is exceeded (*i.e.,* metric resulting in the largest isopleth). The SEL_{cum} metric considers both level and duration of exposure, as well as auditory weighting functions by marine mammal hearing group.

These thresholds are provided in Table 3 below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2018 Technical Guidance, which may be accessed at: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 3—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS Onset acoustic thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	*Cell 2:* $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	*Cell 4:* $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB;	*Cell 6:* $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	*Cell 8:* $L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	*Cell 9:* $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	*Cell 10:* $L_{E,OW,24h}$: 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 µPa, and cumulative sound exposure level (L_E) has a reference value of 1µPa^{2}s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds, which include source levels and transmission loss coefficient.

The planned survey entails the use of HRG equipment. The distance to the isopleth corresponding to the threshold for Level B harassment was calculated for all HRG equipment with the potential to result in harassment of marine mammals. NMFS has developed methodology for determining the rms sound pressure level (SPL_{rms}) at the 160-dB isopleth for the purposes of estimating take by Level B harassment resulting from exposure to HRG survey equipment (NMFS, 2019). This methodology incorporates frequency and some directionality to refine estimated ensonified zones. Mayflower used the methods specified in the interim methodology (NMFS, 2019). The Level B harassment zone for the Innomar parametric sub-bottom profiler was calculated using this methodology, with additional modifications to account for energy emitted outside of the primary beam of the source. For sources that operate with different beam widths, the maximum beam width was used. The lowest frequency of the source was used when calculating the absorption coefficient. The formulas used to apply the methodology are described in detail in Appendix B of the IHA application.

NMFS considers the data provided by Crocker and Fratantonio (2016) to represent the best available information on source levels associated with HRG equipment and therefore recommends that source levels provided by Crocker and Fratantonio (2016) be incorporated in the method described above to estimate isopleth distances to the Level B harassment threshold. In cases when the source level for a specific type of HRG equipment is not provided in Crocker and Fratantonio (2016), NMFS recommends that either the source levels provided by the manufacturer be used, or, in instances where source levels provided by the manufacturer are unavailable or unreliable, a proxy from Crocker and Fratantonio (2016) be used instead. Table 1 shows the HRG equipment types that may be used during the planned surveys and the sound levels associated with those HRG equipment types. Tables 2 and 4 of Appendix B in the IHA application shows the literature sources for the sound source levels that are shown in Table 1 and that were incorporated into the modeling of Level B isopleth distances to the Level B harassment threshold.

Results of modeling using the methodology described above indicated that, of the HRG survey equipment planned for use by Mayflower that has the potential to result in harassment of marine mammals, sound produced by the Geomarine Geo-Spark 400 tip sparker would propagate furthest to the Level B harassment threshold (Table 4); therefore, for the purposes of the exposure analysis, it was assumed the Geomarine Geo-Spark 400 tip sparker would be active during the entire duration of the surveys. Thus the distance to the isopleth corresponding to the threshold for Level B harassment for the Geomarine Geo-Spark 400 tip sparker (estimated at 141 m; Table 4) was used as the basis of the take calculation for all marine mammals. Note that this results in a conservative estimate of the total ensonified area resulting from the planned activities as Mayflower may not operate the Geomarine Geo-Spark 400 tip sparker during the entire planned survey, and for any survey segments in which it is not ultimately operated, the distance to the Level B harassment threshold would be less than 141 m (Table 4). However, as Mayflower cannot predict the precise number of survey days that will require the use of the Geomarine Geo-Spark 400 tip sparker, it was assumed that it would be operated during the entire duration of the planned surveys.

TABLE 4—MODELED RADIAL DISTANCES FROM HRG SURVEY EQUIPMENT TO ISOPLETHS CORRESPONDING TO LEVEL A AND LEVEL B HARASSMENT THRESHOLDS

Sound source	Radial distance to Level A harassment threshold (m) *				Radial distance to Level B harassment Threshold (m)
	Low frequency cetaceans	Mid frequency cetaceans	High frequency cetaceans	Phocid pinnipeds (underwater)	All marine mammals
Innomar SES–2000 Medium-100 Parametric	<1	<1	60	<1	116
Edgetech 2000–DSS	<1	<1	3	<1	5
Geomarine Geo-Spark 400 tip sparker (800 Joules)	<1	<1	8	<1	141

* Distances to the Level A harassment threshold based on the larger of the dual criteria (peak SPL and SEL_{cum}) are shown. For all sources the SEL_{cum} metric resulted in larger isopleth distances.

Predicted distances to Level A harassment isopleths, which vary based on marine mammal functional hearing groups (Table 3), were also calculated. The updated acoustic thresholds for impulsive sounds (such as HRG survey equipment) contained in the Technical Guidance (NMFS, 2018) were presented as dual metric acoustic thresholds using both cumulative sound exposure level (SEL_{cum}) and peak sound pressure level metrics. As dual metrics, NMFS considers onset of PTS (Level A harassment) to have occurred when either one of the two metrics is exceeded (*i.e.,* the metric resulting in the largest isopleth). The SEL_{cum} metric considers both level and duration of exposure, as well as auditory weighting functions by marine mammal hearing group.

Modeling of distances to isopleths corresponding to the Level A harassment threshold was performed for all types of HRG equipment planned for use with the potential to result in harassment of marine mammals. Mayflower used a new model developed by JASCO to calculate distances to Level A harassment isopleths based on both the peak SPL and the SEL_{cum} metric. For the peak SPL metric, the model is a series of equations that accounts for both seawater absorption and HRG equipment beam patterns (for all HRG sources with beam widths larger than 90°, it was assumed these sources were omnidirectional). For the SEL_{cum} metric, a model was developed that accounts for the hearing sensitivity of the marine mammal group, seawater absorption, and beam width for downwards-facing transducers. Details of the modeling methodology for both the peak SPL and SEL_{cum} metrics are provided in Appendix A of the IHA application. This model entails the following steps:

1. Weighted broadband source levels were calculated by assuming a flat spectrum between the source minimum and maximum frequency, weighted the spectrum according to the marine mammal hearing group weighting function (NMFS 2018), and summed across frequency;

2. Propagation loss was modeled as a function of oblique range;

3. Per-pulse SEL was modeled for a stationary receiver at a fixed distance off a straight survey line, using a vessel transit speed of 3.5 knots and source-specific pulse length and repetition rate. The off-line distance is referred to as the closest point of approach (CPA) and was performed for CPA distances between 1 m and 10 km. The survey line length was modeled as 10 km long (analysis showed longer survey lines increased SEL by a negligible amount). SEL is calculated as $SPL + 10 \log_{10} T/15$ dB, where T is the pulse duration;

4. The SEL for each survey line was calculated to produce curves of weighted SEL as a function of CPA distance; and

5. The curves from Step 4 above were used to estimate the CPA distance to the impact criteria.

We note that in the modeling methods described above and in Appendix A of the IHA application, sources that operate with a repetition rate greater than 10 Hz were assessed with the non-impulsive (intermittent) source criteria while sources with a repetition rate equal to or less than 10 Hz were assessed with the impulsive source criteria. NMFS does not necessarily agree with this step in the modeling assessment, which results in nearly all HRG sources being classified as impulsive; however, we note that the classification of the majority of HRG sources as impulsive results in more conservative modeling results. Thus, we have assessed the potential for Level A harassment to result from the planned activities based on the modeled Level A zones with the acknowledgement that these zones are likely conservative.

Modeled isopleth distances to Level A harassment thresholds for all types of HRG equipment and all marine mammal functional hearing groups are shown in Table 4. The dual criteria (peak SPL and SEL_{cum}) were applied to all HRG sources using the modeling methodology as described above, and the largest isopleth distances for each functional hearing group were then carried forward in the exposure analysis to be conservative. For all HRG sources, the SEL_{cum} metric resulted in larger isopleth distances. Distances to the Level A harassment threshold based on the larger of the dual criteria (peak SPL and SEL_{cum}) are shown in Table 4.

Modeled distances to isopleths corresponding to the Level A harassment threshold are very small (<1 m) for three of the four marine mammal functional hearing groups that may be impacted by the planned activities (*i.e.,* low frequency and mid frequency cetaceans, and phocid pinnipeds; see Table 4). Based on the very small Level A harassment zones for these functional hearing groups, the potential for species within these functional hearing groups to be taken by Level A harassment is considered so low as to be discountable. For harbor porpoises (a high frequency specialist), the largest modeled distance to the Level A harassment threshold for the high frequency functional hearing group was 60 m (Table 4). However, as noted above, modeled distances to isopleths corresponding to the Level A harassment threshold are assumed to be conservative. Further, the Innomar source uses a very narrow beam width (two degrees) and the distances to the Level A harassment isopleths are eight meters or less for the other two sources. Level A harassment would also be more likely to occur at close approach to the sound source or as a result of longer duration exposure to the sound source, and mitigation measures—including a 100-m exclusion zone for harbor

porpoises—are expected to minimize the potential for close approach or longer duration exposure to active HRG sources. In addition, harbor porpoises are a notoriously shy species which is known to avoid vessels, and would also be expected to avoid a sound source prior to that source reaching a level that would result in injury (Level A harassment). Therefore, we have determined that the potential for take by Level A harassment of harbor porpoises is so low as to be discountable. As NMFS has determined that the likelihood of take of any marine mammals in the form of Level A harassment occurring as a result of the planned surveys is so low as to be discountable, we therefore have not authorized the take by Level A harassment of any marine mammals.

Marine Mammal Occurrence

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations.

The habitat-based density models produced by the Duke University Marine Geospatial Ecology Laboratory (Roberts *et al.,* 2016, 2017, 2018) represent the best available information regarding marine mammal densities in the planned survey area. The density data presented by Roberts *et al.* (2016, 2017, 2018) incorporates aerial and shipboard line-transect survey data from NMFS and other organizations and incorporates data from 8 physiographic and 16 dynamic oceanographic and biological covariates, and controls for the influence of sea state, group size, availability bias, and perception bias on the probability of making a sighting. These density models were originally developed for all cetacean taxa in the U.S. Atlantic (Roberts *et al.,* 2016). In subsequent years, certain models have been updated on the basis of additional data as well as certain methodological improvements. Our evaluation of the changes leads to a conclusion that these represent the best scientific evidence available. More information, including the model results and supplementary information for each model, is available online at *seamap.env.duke.edu/models/Duke-EC-GOM-2015/.* Marine mammal density estimates in the project area (animals/km^2) were obtained using these model results (Roberts *et al.,* 2016, 2017, 2018). The updated models incorporate additional sighting data, including sightings from the NOAA Atlantic Marine Assessment Program for Protected Species (AMAPPS) surveys from 2010–2014 (NEFSC & SEFSC, 2011, 2012, 2014a, 2014b, 2015, 2016).

For the exposure analysis, density data from Roberts *et al.* (2016, 2017, 2018) were mapped using a geographic information system (GIS). These data provide abundance estimates for species or species guilds within 10 km x 10 km grid cells (100 km^2) on a monthly or annual basis, depending on the species. In order to select a representative sample of grid cells in and near the Project Area, a 10-km wide perimeter around the Lease Area and an 8-km wide perimeter around the cable route were created in GIS (ESRI 2017). The perimeters were then used to select grid cells near the Project Area containing the most recent monthly or annual estimates for each species in the Roberts *et al.* (2016, 2017, 2018) data. The average monthly abundance for each species in each survey area (deep-water and shallow-water) was calculated as the mean value of the grid cells within each survey portion in each month (July through September), and then converted for density (individuals/km^2) by dividing by 100 km^2 (Tables 5 and 6).

Roberts *et al.* (2018) produced density models for all seals and did not differentiate by seal species. Because the seasonality and habitat use by gray seals roughly overlaps with that of harbor seals in the survey areas, it was assumed that modeled takes of seals could occur to either of the respective species, thus the total number of modeled takes for seals was applied to each species.

TABLE 5—AVERAGE MONTHLY DENSITIES FOR SPECIES IN THE LEASE AREA AND DEEP-WATER SECTION OF THE CABLE ROUTE

Species	Estimated monthly density (individuals/km^2)		
	July	August	September
Fin whale	0.0033	0.0029	0.0025
Humpback whale	0.0011	0.0005	0.0011
Minke whale	0.0010	0.0007	0.0008
North Atlantic right whale	0.0000	0.0000	0.0000
Sei whale	0.0001	0.0000	0.0001
Atlantic white-sided dolphin	0.0446	0.0243	0.0246
Bottlenose dolphin	0.0516	0.0396	0.0494
Harbor porpoise	0.0125	0.0114	0.0093
Pilot whale	0.0066	0.0066	0.0066
Risso's dolphin	0.0005	0.0009	0.0007
Common dolphin	0.0614	0.1069	0.1711
Sperm whale	0.0004	0.0004	0.0002
Seals (harbor and gray)	0.0061	0.0033	0.0040

TABLE 6—AVERAGE MONTHLY DENSITIES FOR SPECIES IN THE SHALLOW-WATER SECTION OF THE CABLE ROUTE

Species	Estimated monthly density (individuals/km^2)		
	July	August	September
Fin whale	0.0003	0.0003	0.0003
Humpback whale	0.0001	0.0000	0.0001
Minke whale	0.0000	0.0000	0.0000
North Atlantic right whale	0.0000	0.0000	0.0000
Sei whale	0.0000	0.0000	0.0000
Atlantic white-sided dolphin	0.0006	0.0005	0.0008

TABLE 6—AVERAGE MONTHLY DENSITIES FOR SPECIES IN THE SHALLOW-WATER SECTION OF THE CABLE ROUTE—Continued

Species	Estimated monthly density (individuals/km²)		
	July	August	September
Bottlenose dolphin	0.4199	0.3211	0.3077
Harbor porpoise	0.0023	0.0037	0.0036
Pilot whale	0.0000	0.0000	0.0000
Risso's dolphin	0.0000	0.0000	0.0000
Common dolphin	0.0002	0.0006	0.0009
Sperm whale	0.0000	0.0000	0.0000
Seals (harbor and gray)	0.0281	0.0120	0.0245

Take Calculation and Estimation

Here we describe how the information provided above is brought together to produce a quantitative take estimate.

In order to estimate the number of marine mammals predicted to be exposed to sound levels that would result in harassment, radial distances to predicted isopleths corresponding to harassment thresholds are calculated, as described above. Those distances are then used to calculate the area(s) around the HRG survey equipment predicted to be ensonified to sound levels that exceed harassment thresholds. The area estimated to be ensonified to relevant thresholds in a single day is then calculated, based on areas predicted to be ensonified around the HRG survey equipment and the estimated trackline distance traveled per day by the survey vessel. Mayflower estimates that the survey vessel in the Lease Area and deep-water sections of the cable route will achieve a maximum daily trackline of 110 km per day and the survey vessels in the shallow-water section of the cable route will achieve a maximum of 55 km per day during planned HRG surveys. This distance accounts for survey vessels traveling at roughly 3 knots and accounts for non-active survey periods.

Based on the maximum estimated distance to the Level B harassment threshold of 141 m (Table 4) and the maximum estimated daily track line distance of 110 km, an area of 31.1 km² would be ensonified to the Level B harassment threshold each day in the Lease Area and deep-water section of the cable route during Mayflower's planned surveys. During 90 days of anticipated survey activity over the three month period (July through September), approximately 30 days of survey activity are expected each month, for an average of 933 km² ensonified to the Level B harassment threshold in the Lease Area and deep-water section of the cable route each month of survey activities.

Similarly, based on the maximum estimated distance to the Level B harassment threshold of 141 m (Table 4) and the maximum estimated daily track line distance of 55 km, an area of 15.6 km² would be ensonified to the Level B harassment threshold each day in the shallow-water section of the cable route. During 125 days of anticipated survey activity over the three month period (July through September), approximately 41.7 days of survey activity (split among two vessels) are expected each month, for an average of 650 km² ensonified to the Level B harassment threshold in the shallow-water section of the cable route each month of survey activities.

As described above, this is a conservative estimate as it assumes the HRG sources that result in the greatest isopleth distances to the Level B harassment threshold would be operated at all times during all 215 vessel days.

The estimated numbers of marine mammals that may be taken by Level B harassment were calculated by multiplying the monthly density for each species in each survey area (Tables 5 and 6) by the respective monthly ensonified area within each survey section. The results were then summed to determine the total estimated take (Table 7).

TABLE 7—TOTAL NUMBERS OF AUTHORIZED INCIDENTAL TAKES OF MARINE MAMMALS AND TAKES AS A PERCENTAGE OF POPULATION

Species	Calculated take by survey region		Total calculated takes by Level B harassment	Authorized takes by Level A harassment	Authorized takes by Level B harassment [b]	Total authorized instances of take as a percentage of population [a]
	Lease area and deep-water cable route	Shallow-water cable route				
Fin whale	8.3	0.6	8.9	0	9	0.3
Humpback whale	2.9	0.2	3.1	0	4	0.2
Minke whale	3.4	0.2	3.6	0	4	0.1
North Atlantic right whale	0.9	0	0.9	0	[c] 3	0.8
Sei whale	0.3	0	0.3	0	[c] 2	0.4
Atlantic white-sided dolphin	109.3	1.4	110.7	0	111	0.1
Bottlenose dolphin	131.0	680.4	811.5	0	812	1.0
Harbor porpoise	36.4	7	43.4	0	44	0.1
Pilot whale	18.4	0	18.4	0	19	0.1
Risso's dolphin	1.7	0	1.7	0	[b] 6	0.1
Common dolphin	316.5	1.1	317.6	0	318	0.3
Sperm whale	0.8	0	0.8	0	[c] 2	<0.01

TABLE 7—TOTAL NUMBERS OF AUTHORIZED INCIDENTAL TAKES OF MARINE MAMMALS AND TAKES AS A PERCENTAGE OF POPULATION—Continued

Species	Calculated take by survey region		Total calculated takes by Level B harassment	Authorized takes by Level A harassment	Authorized takes by Level B harassment [b]	Total authorized instances of take as a percentage of population [a]
	Lease area and deep-water cable route	Shallow-water cable route				
Seals (harbor and gray)	40.4	152.8	193.2	0	194	0.7

[a] Calculations of percentage of stock taken are based on the best available abundance estimate as shown in Table 2. In most cases the best available abundance estimate is provided by Roberts *et al.* (2016, 2017, 2018), when available, to maintain consistency with density estimates derived from Roberts *et al.* (2016, 2017, 2018). For bottlenose dolphins and seals, Roberts *et al.* (2016, 2017, 2018) provides only a single abundance estimate and does not provide abundance estimates at the stock or species level (respectively), so the abundance estimate used to estimate percentage of stock taken for bottlenose dolphins is derived from NMFS SARs (Hayes *et al.,* 2019). For seals, NMFS proposes to authorize 194 takes of seals as a guild by Level B harassment and assumes take could occur to either species. For the purposes of estimating percentage of stock taken, the NMFS SARs abundance estimate for gray seals was used as the abundance of gray seals is lower than that of harbor seals (Hayes *et al.,* 2019).

[b] Authorized take equal to calculated take rounded up to next integer, or mean group size.

[c] Authorized take increased to mean group size (Palka *et al.,* 2017; Kraus *et al.,* 2016).

Using the take methodology approach described above, the take estimates for Risso's dolphin, sei whale, North Atlantic right whale, and sperm whale were less than the average group sizes estimated for these species (Table 7). However, information on the social structures of these species indicates these species are likely to be encountered in groups. Therefore it is reasonable to conservatively assume that one group of each of these species will be taken during the planned survey. We have therefore authorized the take of the average group size for these species to account for the possibility that the planned survey encounters a group of either of these species (Table 7).

As described above, NMFS has determined that the likelihood of take of any marine mammals in the form of Level A harassment occurring as a result of the planned surveys is so low as to be discountable; therefore, we have not authorized take of any marine mammals by Level A harassment.

Mitigation

In order to issue an IHA under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned); and

(2) the practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Mitigation Measures

NMFS has required the following mitigation measures be implemented during Mayflower's planned marine site characterization surveys.

Marine Mammal Exclusion Zones, Buffer Zone and Monitoring Zone

Marine mammal exclusion zones (EZ) must be established around the HRG survey equipment and monitored by protected species observers (PSO) during HRG surveys as follows:

- A 500-m EZ is required for North Atlantic right whales; and
- A 100-m EZ is required for all other marine mammals (with the exception of certain small dolphin species and pinnipeds specified below).

If a marine mammal is detected approaching or entering the EZs during the planned survey, the vessel operator must adhere to the shutdown procedures described below. In addition to the EZs described above, PSOs must visually monitor a 200 m Buffer Zone. During use of acoustic sources with the potential to result in marine mammal harassment (*i.e.,* anytime the acoustic source is active, including ramp-up), occurrences of marine mammals within the Buffer Zone (but outside the EZs) must be communicated to the vessel operator to prepare for potential shutdown of the acoustic source. The Buffer Zone is not applicable when the EZ is greater than 100 meters. PSOs are also required to observe a 500-m Monitoring Zone and record the presence of all marine mammals within this zone. In addition, any marine mammals observed within 141 m of the active HRG equipment operating at or below 180 kHz must be documented by PSOs as taken by Level B harassment. The zones described above must be based upon the radial distance from the active equipment (rather than being based on distance from the vessel itself).

Visual Monitoring

A minimum of one NMFS-approved PSO must be on duty and conducting visual observations at all times during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset) and 30 minutes prior to and during nighttime ramp-ups of HRG equipment. Visual monitoring

must begin no less than 30 minutes prior to ramp-up of HRG equipment and must continue until 30 minutes after use of the acoustic source ceases or until 30 minutes past sunset. PSOs must establish and monitor the applicable EZs, Buffer Zone and Monitoring Zone as described above. Visual PSOs must coordinate to ensure 360° visual coverage around the vessel from the most appropriate observation posts, and must conduct visual observations using binoculars and the naked eye while free from distractions and in a consistent, systematic, and diligent manner. PSOs must estimate distances to marine mammals located in proximity to the vessel and/or relevant using range finders. It is the responsibility of the Lead PSO on duty to communicate the presence of marine mammals as well as to communicate and enforce the action(s) that are necessary to ensure mitigation and monitoring requirements are implemented as appropriate. Position data must be recorded using hand-held or vessel global positioning system (GPS) units for each confirmed marine mammal sighting.

Pre-Clearance of the Exclusion Zones

Prior to initiating HRG survey activities, Mayflower must implement a 30-minute pre-clearance period. During pre-clearance monitoring (*i.e.,* before ramp-up of HRG equipment begins), the Buffer Zone will also act as an extension of the 100-m EZ in that observations of marine mammals within the 200-m Buffer Zone will also preclude HRG operations from beginning. During this period, PSOs must ensure that no marine mammals are observed within 200 m of the survey equipment (500 m in the case of North Atlantic right whales). HRG equipment must not start up until this 200-m zone (or, 500-m zone in the case of North Atlantic right whales) is clear of marine mammals for at least 30 minutes. The vessel operator must notify a designated PSO of the planned start of HRG survey equipment as agreed upon with the lead PSO; the notification time should not be less than 30 minutes prior to the planned initiation of HRG equipment order to allow the PSOs time to monitor the EZs and Buffer Zone for the 30 minutes of pre-clearance. A PSO conducting pre-clearance observations must be notified again immediately prior to initiating active HRG sources.

If a marine mammal were observed within the relevant EZs or Buffer Zone during the pre-clearance period, initiation of HRG survey equipment must not begin until the animal(s) has been observed exiting the respective EZ or Buffer Zone, or, until an additional time period has elapsed with no further sighting (*i.e.,* minimum 15 minutes for small odontocetes and seals, and 30 minutes for all other species). The pre-clearance requirement includes small delphinoids that approach the vessel (*e.g.,* bow ride). PSOs must also continue to monitor the zone for 30 minutes after survey equipment is shut down or survey activity has concluded.

Ramp-Up of Survey Equipment

When technically feasible, a ramp-up procedure must be used for geophysical survey equipment capable of adjusting energy levels at the start or re-start of survey activities. The ramp-up procedure must be used at the beginning of HRG survey activities in order to provide additional protection to marine mammals near the Project Area by allowing them to detect the presence of the survey and vacate the area prior to the commencement of survey equipment operation at full power. Ramp-up of the survey equipment must not begin until the relevant EZs and Buffer Zone has been cleared by the PSOs, as described above. HRG equipment must be initiated at their lowest power output and must be incrementally increased to full power. If any marine mammals are detected within the EZs or Buffer Zone prior to or during ramp-up, the HRG equipment must be shut down (as described below).

Shutdown Procedures

If an HRG source is active and a marine mammal is observed within or entering a relevant EZ (as described above) an immediate shutdown of the HRG survey equipment is required. When shutdown is called for by a PSO, the acoustic source must be immediately deactivated and any dispute resolved only following deactivation. Any PSO on duty has the authority to delay the start of survey operations or to call for shutdown of the acoustic source if a marine mammal is detected within the applicable EZ. The vessel operator must establish and maintain clear lines of communication directly between PSOs on duty and crew controlling the HRG source(s) to ensure that shutdown commands are conveyed swiftly while allowing PSOs to maintain watch. Subsequent restart of the HRG equipment must only occur after the marine mammal has either been observed exiting the relevant EZ, or, until an additional time period has elapsed with no further sighting of the animal within the relevant EZ (*i.e.,* 15 minutes for small odontocetes and seals, and 30 minutes for large whales).

Upon implementation of shutdown, the HRG source may be reactivated after the marine mammal that triggered the shutdown has been observed exiting the applicable EZ (*i.e.,* the animal is not required to fully exit the Buffer Zone where applicable) or, following a clearance period of 15 minutes for small odontocetes and seals and 30 minutes for all other species with no further observation of the marine mammal(s) within the relevant EZ. If the HRG equipment shuts down for brief periods (*i.e.,* less than 30 minutes) for reasons other than mitigation (*e.g.,* mechanical or electronic failure) the equipment may be re-activated as soon as is practicable at full operational level, without 30 minutes of pre-clearance, only if PSOs have maintained constant visual observation during the shutdown and no visual detections of marine mammals occurred within the applicable EZs and Buffer Zone during that time. For a shutdown of 30 minutes or longer, or if visual observation was not continued diligently during the pause, pre-clearance observation is required, as described above.

The shutdown requirement is waived for certain genera of small delphinids (*i.e., Delphinus, Lagenorhynchus, and Tursiops)* and pinnipeds (gray and harbor seals) under certain circumstances. If a delphinid(s) from these genera or seal(s) is visually detected approaching the vessel (*i.e.,* to bow ride) or towed survey equipment, shutdown is not required. If there is uncertainty regarding identification of a marine mammal species (*i.e.,* whether the observed marine mammal(s) belongs to one of the delphinid genera for which shutdown is waived), PSOs must use best professional judgment in making the decision to call for a shutdown.

If a species for which authorization has not been granted, or, a species for which authorization has been granted but the authorized number of takes have been met, approaches or is observed within the area encompassing the Level B harassment isopleth (141 m), shutdown must occur.

Vessel Strike Avoidance

Vessel strike avoidance measures include, but are not limited to, the following, except under circumstances when complying with these requirements would put the safety of the vessel or crew at risk:

- All vessel operators and crew will maintain vigilant watch for cetaceans and pinnipeds, and slow down or stop their vessel to avoid striking these protected species;
- All survey vessels, regardless of size, must observe a 10-knot speed

restriction in DMAs designated by NMFS for the protection of North Atlantic right whales from vessel strikes. Note that this requirement includes vessels, regardless of size, to adhere to a 10 knot speed limit in DMAs, not just vessels 65 ft or greater in length;

- All vessel operators will reduce vessel speed to 10 knots (18.5 km/hr) or less when any large whale, any mother/calf pairs, large assemblages of non-delphinoid cetaceans are observed near (within 100 m (330 ft)) an underway vessel;
- All vessels will maintain a separation distance of 500 m (1,640 ft) or greater from any sighted North Atlantic right whale;
- If underway, vessels must steer a course away from any sighted North Atlantic right whale at 10 knots (18.5 km/hr) or less until the 500-m (1,640 ft) minimum separation distance has been established. If a North Atlantic right whale is sighted in a vessel's path, or within 100 m (330 ft) to an underway vessel, the underway vessel must reduce speed and shift the engine to neutral. Engines will not be engaged until the North Atlantic right whale has moved outside of the vessel's path and beyond 100 m. If stationary, the vessel must not engage engines until the North Atlantic right whale has moved beyond 100 m;
- All vessels will maintain a separation distance of 100 m (330 ft) or greater from any sighted non-delphinoid cetacean. If sighted, the vessel underway must reduce speed and shift the engine to neutral, and must not engage the engines until the non-delphinoid cetacean has moved outside of the vessel's path and beyond 100 m. If a survey vessel is stationary, the vessel will not engage engines until the non-delphinoid cetacean has moved out of the vessel's path and beyond 100 m;
- All vessels will maintain a separation distance of 50 m (164 ft) or greater from any sighted delphinoid cetacean. Any vessel underway remain parallel to a sighted delphinoid cetacean's course whenever possible, and avoid excessive speed or abrupt changes in direction. Any vessel underway reduces vessel speed to 10 knots (18.5 km/hr) or less when pods (including mother/calf pairs) or large assemblages of delphinoid cetaceans are observed. Vessels may not adjust course and speed until the delphinoid cetaceans have moved beyond 50 m and/or the abeam of the underway vessel;
- All vessels will maintain a separation distance of 50 m (164 ft) or greater from any sighted pinniped; and
- All vessels underway will not divert or alter course in order to approach any whale, delphinoid cetacean, or pinniped. Any vessel underway will avoid excessive speed or abrupt changes in direction to avoid injury to the sighted cetacean or pinniped.

Project-specific training will be conducted for all vessel crew prior to the start of survey activities. Confirmation of the training and understanding of the requirements will be documented on a training course log sheet. Signing the log sheet will certify that the crew members understand and will comply with the necessary requirements throughout the survey activities.

Passive Acoustic Monitoring

Mayflower will also employ passive acoustic monitoring (PAM) to support monitoring during night time operations to provide for acquisition of species detections at night. While PAM is not typically required by NMFS for HRG surveys, it may a provide additional benefit as a mitigation and monitoring measure to further limit potential exposure to underwater sound at levels that could result in injury or behavioral harassment.

Based on our evaluation of the applicant's planned measures, as well as other measures considered by NMFS, NMFS has determined that the required mitigation measures provide the means effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an IHA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the planned action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

Monitoring Measures

As described above, visual monitoring must be performed by qualified and NMFS-approved PSOs. Mayflower must use independent, dedicated, trained PSOs, meaning that the PSOs must be employed by a third-party observer provider, must have no tasks other than to conduct observational effort, collect data, and communicate with and instruct relevant vessel crew with regard to the presence of marine mammals and mitigation requirements (including brief alerts regarding maritime hazards), and must have successfully completed an approved PSO training course appropriate for their designated task. Mayflower must provide resumes of all proposed PSOs (including alternates) to NMFS for review and approval prior to the start of survey operations.

During survey operations (*e.g.,* any day on which use of an HRG source is planned to occur), a minimum of one PSO must be on duty and conducting visual observations at all times on all active survey vessels during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset) and nighttime ramp-ups of HRG equipment. Visual monitoring must begin no less than 30 minutes prior to initiation of HRG survey equipment and

must continue until one hour after use of the acoustic source ceases or until 30 minutes past sunset. PSOs must coordinate to ensure 360° visual coverage around the vessel from the most appropriate observation posts, and must conduct visual observations using binoculars and the naked eye while free from distractions and in a consistent, systematic, and diligent manner. PSOs may be on watch for a maximum of four consecutive hours followed by a break of at least two hours between watches and may conduct a maximum of 12 hours of observation per 24-hour period. In cases where multiple vessels are surveying concurrently, any observations of marine mammals must be communicated to PSOs on all survey vessels.

PSOs must be equipped with binoculars and have the ability to estimate distances to marine mammals located in proximity to the vessel and/or exclusion zone using range finders. Reticulated binoculars will also be available to PSOs for use as appropriate based on conditions and visibility to support the monitoring of marine mammals. Position data must be recorded using hand-held or vessel GPS units for each sighting. Observations must take place from the highest available vantage point on the survey vessel. General 360-degree scanning must occur during the monitoring periods, and target scanning by the PSO must occur when alerted of a marine mammal presence.

During good conditions (*e.g.,* daylight hours; Beaufort sea state (BSS) 3 or less), to the maximum extent practicable, PSOs must conduct observations when the acoustic source is not operating for comparison of sighting rates and behavior with and without use of the acoustic source and between acquisition periods. Any observations of marine mammals by crew members aboard any vessel associated with the survey must be relayed to the PSO team.

Data on all PSO observations must be recorded based on standard PSO collection requirements. This includes dates, times, and locations of survey operations; dates and times of observations, location and weather; details of marine mammal sightings (*e.g.,* species, numbers, behavior); and details of any observed marine mammal take that occurs (*e.g.,* noted behavioral disturbances).

Reporting Measures

Within 90 days after completion of survey activities, a final technical report must be provided to NMFS that fully documents the methods and monitoring protocols, summarizes the data recorded during monitoring, summarizes the number of marine mammals estimated to have been taken during survey activities (by species, when known), summarizes the mitigation actions taken during surveys (including what type of mitigation and the species and number of animals that prompted the mitigation action, when known), and provides an interpretation of the results and effectiveness of all mitigation and monitoring. Any recommendations made by NMFS must be addressed in the final report prior to acceptance by NMFS.

In addition to the final technical report, Mayflower must provide the reports described below as necessary during survey activities. In the unanticipated event that Mayflower's activities lead to an injury (Level A harassment) of a marine mammal, Mayflower must immediately cease the specified activities and report the incident to the NMFS Office of Protected Resources Permits and Conservation Division and the NMFS Northeast Regional Stranding Coordinator. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Name and type of vessel involved;
- Vessel's speed during and leading up to the incident;
- Description of the incident;
- Status of all sound source use in the 24 hours preceding the incident;
- Water depth;
- Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities must not resume until NMFS is able to review the circumstances of the event. NMFS will work with Mayflower to minimize reoccurrence of such an event in the future. Mayflower must not resume activities until notified by NMFS.

In the event that Mayflower personnel discover an injured or dead marine mammal, Mayflower must report the incident to the OPR Permits and Conservation Division and the NMFS Northeast Regional Stranding Coordinator as soon as feasible. The report must include the following information:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal was discovered.

In the unanticipated event of a ship strike of a marine mammal by any vessel involved in the activities covered by the IHA, Mayflower must report the incident to the NMFS OPR Permits and Conservation Division and the NMFS Northeast Regional Stranding Coordinator as soon as feasible. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Species identification (if known) or description of the animal(s) involved;
- Vessel's speed during and leading up to the incident;
- Vessel's course/heading and what operations were being conducted (if applicable);
- Status of all sound sources in use;
- Description of avoidance measures/requirements that were in place at the time of the strike and what additional measures were taken, if any, to avoid strike;
- Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, visibility) immediately preceding the strike;
- Estimated size and length of animal that was struck;
- Description of the behavior of the marine mammal immediately preceding and following the strike;
- If available, description of the presence and behavior of any other marine mammals immediately preceding the strike;
- Estimated fate of the animal (*e.g.,* dead, injured but alive, injured and moving, blood or tissue observed in the water, status unknown, disappeared); and
- To the extent practicable, photographs or video footage of the animal(s).

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival

(50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, our analysis applies to all the species listed in Table 7, given that NMFS expects the anticipated effects of the planned survey to be similar in nature. NMFS does not anticipate that serious injury or mortality would result from HRG surveys, even in the absence of mitigation, and no serious injury or mortality is authorized. As discussed in the *Potential Effects* section of the notice of proposed IHA (85 FR 31856; May 27, 2020), non-auditory physical effects and vessel strike are not expected to occur. We expect that potential takes would be in the form of short-term Level B behavioral harassment in the form of temporary avoidance of the area or decreased foraging (if such activity were occurring), reactions that are considered to be of low severity and with no lasting biological consequences (*e.g.,* Southall *et al.,* 2007). As described above, Level A harassment is not expected to result given the nature of the operations, the anticipated size of the Level A harassment zones, the density of marine mammals in the area, and the required shutdown zones.

Effects on individuals that are taken by Level B harassment, on the basis of reports in the literature as well as monitoring from other similar activities, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring). Most likely, individuals will simply move away from the sound source and temporarily avoid the area where the survey is occurring. We expect that any avoidance of the survey area by marine mammals would be temporary in nature and that any marine mammals that avoid the survey area during the survey activities would not be permanently displaced. Even repeated Level B harassment of some small subset of an overall stock is unlikely to result in any significant realized decrease in viability for the affected individuals, and thus would not result in any adverse impact to the stock as a whole.

Regarding impacts to marine mammal habitat, prey species are mobile, and are broadly distributed throughout the Project Area and the footprint of the activity is small; therefore, marine mammals that may be temporarily displaced during survey activities are expected to be able to resume foraging once they have moved away from areas with disturbing levels of underwater noise. Because of the availability of similar habitat and resources in the surrounding area the impacts to marine mammals and the food sources that they utilize are not expected to cause significant or long-term consequences for individual marine mammals or their populations. The HRG survey equipment itself will not result in physical habitat disturbance. Avoidance of the area around the HRG survey activities by marine mammal prey species is possible. However, any avoidance by prey species would be expected to be short term and temporary.

ESA-listed species for which takes are authorized are North Atlantic right, fin, sei, and sperm whales, and these effects are anticipated to be limited to lower level behavioral effects. The planned survey is not anticipated to affect the fitness or reproductive success of individual animals. Since impacts to individual survivorship and fecundity are unlikely, the planned survey is not expected to result in population-level effects for any ESA-listed species or alter current population trends of any ESA-listed species.

The status of the North Atlantic right whale population is of heightened concern and, therefore, merits additional analysis. NMFS has rigorously assessed potential impacts to right whales from this survey. We have established a 500-m shutdown zone for right whales which is precautionary considering the Level B harassment isopleth for the largest source utilized (*i.e.* GeoMarine Geo-Source 400 tip sparker) is estimated to be 141 m.

The Project Area encompasses or is in close proximity to feeding biologically important areas (BIAs) for right whales (February–April), humpback whales (March–December), fin whales (March–October), and sei whales (May–November) as well as a migratory BIA for right whales (March–April and November–December). Most of these feeding BIAs are extensive and sufficiently large (705 km^2 and 3,149 km^2 for right whales; 47,701 km^2 for humpback whales; 2,933 km^2 for fin whales; and 56,609 km^2 for sei whales), and the acoustic footprint of the planned survey is sufficiently small, that feeding opportunities for these whales would not be reduced appreciably. Any whales temporarily displaced from the Project Area would be expected to have sufficient remaining feeding habitat available to them, and would not be prevented from feeding in other areas within the biologically important feeding habitat. In addition, any displacement of whales from the BIA or interruption of foraging bouts would be expected to be temporary in nature. Therefore, we do not expect impacts to whales within feeding BIAs to effect the fitness of any large whales.

A migratory BIA for North Atlantic right whales (effective March–April and November–December) extends from Massachusetts to Florida (LaBrecque, *et al.,* 2015). Off the south coast of Massachusetts and Rhode Island, this BIA extends from the coast to beyond the shelf break. The fact that the spatial acoustic footprint of the planned survey is very small relative to the spatial extent of the available migratory habitat means that right whale migration is not expected to be impacted by the p survey. Required vessel strike avoidance measures will also decrease risk of ship strike during migration. NMFS is expanding the standard avoidance measures by requiring that all vessels, regardless of size, adhere to a 10 knot speed limit in any established DMAs. Additionally, limited take by Level B harassment of North Atlantic right whales has been authorized as HRG survey operations are required to shut down at 500 m to minimize the potential for behavioral harassment of this species.

There are several active unusual mortality events (UMEs) occurring in the vicinity of Mayflower's planned surveys. Elevated humpback whale mortalities have occurred along the Atlantic coast from Maine through Florida since January 2016. Of the cases examined, approximately half had evidence of human interaction (ship

strike or entanglement). The UME does not yet provide cause for concern regarding population-level impacts. Despite the UME, the relevant population of humpback whales (the West Indies breeding population, or distinct population segment (DPS)) remains stable. Beginning in January 2017, elevated minke whale strandings have occurred along the Atlantic coast from Maine through South Carolina, with highest numbers in Massachusetts, Maine, and New York. This event does not provide cause for concern regarding population level impacts, as the likely population abundance is greater than 20,000 whales. Elevated North Atlantic right whale mortalities began in June 2017, primarily in Canada. Overall, preliminary findings support human interactions, specifically vessel strikes or rope entanglements, as the cause of death for the majority of the right whales. Elevated numbers of harbor seal and gray seal mortalities were first observed in July 2018 and have occurred across Maine, New Hampshire and Massachusetts. Based on tests conducted so far, the main pathogen found in the seals is phocine distemper virus although additional testing to identify other factors that may be involved in this UME are underway. The UME does not yet provide cause for concern regarding population-level impacts to any of these stocks. For harbor seals, the population abundance is over 75,000 and annual M/SI (345) is well below PBR (2,006) (Hayes *et al.,* 2018). For gray seals, the population abundance in the United States is over 27,000, with an estimated abundance including seals in Canada of approximately 505,000, and abundance is likely increasing in the U.S. Atlantic Exclusive Economic Zone as well as in Canada (Hayes *et al.,* 2018).

Direct physical interactions (ship strikes and entanglements) appear to be responsible for many of the UME humpback and right whale mortalities recorded. The planned HRG survey will require ship strike avoidance measures which would minimize the risk of ship strikes while fishing gear and in-water lines will not be employed as part of the survey. Furthermore, the planned activities are not expected to promote the transmission of infectious disease among marine mammals. The survey is not expected to result in the deaths of any marine mammals or combine with the effects of the ongoing UMEs to result in any additional impacts not analyzed here. Accordingly, Mayflower did not request, and NMFS has not authorized, take of marine mammals by serious injury, or mortality.

The required mitigation measures are expected to reduce the number and/or severity of takes by giving animals the opportunity to move away from the sound source before HRG survey equipment reaches full energy and preventing animals from being exposed to sound levels that have the potential to cause injury (Level A harassment) and more severe Level B harassment during HRG survey activities, even in the biologically important areas described above. No Level A harassment is anticipated or authorized.

NMFS expects that takes would be in the form of short-term Level B behavioral harassment in the form of brief startling reaction and/or temporary vacating of the area, or decreased foraging (if such activity were occurring)—reactions that (at the scale and intensity anticipated here) are considered to be of low severity and with no lasting biological consequences. Since both the source and the marine mammals are mobile, only a smaller area would be ensonified by sound levels that could result in take for only a short period. Additionally, required mitigation measures would reduce exposure to sound that could result in more severe behavioral harassment.

In summary and as described above, the following factors primarily support our determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

- No mortality or serious injury is anticipated or authorized;
- No Level A harassment (PTS) is anticipated;
- Any foraging interruptions are expected to be short term and unlikely to be cause significantly impacts;
- Impacts on marine mammal habitat and species that serve as prey species for marine mammals are expected to be minimal and the alternate areas of similar habitat value for marine mammals are readily available;
- Take is anticipated to be primarily Level B behavioral harassment consisting of brief startling reactions and/or temporary avoidance of the Project Area;
- Survey activities would occur in such a comparatively small portion of the biologically important area for north Atlantic right whale migration, that any avoidance of the Project Area due to activities would not affect migration. In addition, mitigation measures to shut down at 500 m to minimize potential for Level B behavioral harassment would limit both the number and severity of take of the species;
- Similarly, due to the relatively small footprint of the survey activities in relation to the size of a biologically important areas for right, humpback, fin, and sei whales foraging, the survey activities would not affect foraging success of this species; and
- Required mitigation measures, including visual monitoring and shutdowns, are expected to minimize the intensity of potential impacts to marine mammals.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the required monitoring and mitigation measures, NMFS finds that the total marine mammal take from the Mayflower's planned HRG surveys will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The numbers of marine mammals that we authorize to be taken, for all species and stocks, would be considered small relative to the relevant stocks or populations (less than one third of the best available population abundance for all species and stocks) (see Table 7). In fact, the total amount of taking authorized for all species is 1 percent or less for all affected stocks.

Based on the analysis contained herein of the planned activity (including the required mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or

stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an incidental harassment authorization) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (incidental harassment authorizations with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of the IHA qualifies to be categorically excluded from further NEPA review.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally, in this case with the NMFS Greater Atlantic Regional Fisheries Office (GARFO), whenever we propose to authorize take for endangered or threatened species.

The NMFS Office of Protected Resources is authorizing the incidental take of four species of marine mammals which are listed under the ESA: Fin, sei, sperm, and North Atlantic right whales. We requested initiation of consultation under section 7 of the ESA with NMFS GARFO on May 6, 2020, for the issuance of this IHA. On July 22, 2020, NMFS GARFO determined our issuance of the IHA to Mayflower was not likely to adversely affect the North Atlantic right, fin, sei, and sperm whale or the critical habitat of any ESA-listed species or result in the take of any marine mammals in violation of the ESA.

Authorization

NMFS has issued an IHA to Mayflower for the potential harassment of small numbers of 14 marine mammal species incidental to the conducting marine site characterization surveys offshore of Massachusetts in the area of the Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf (OCS–A 0521) and along a potential submarine cable route to landfall at Falmouth, Massachusetts, provided the previously mentioned mitigation, monitoring and reporting requirements are followed.

Dated: July 23, 2020.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2020–16357 Filed 7–28–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA253]

Schedules for Atlantic Shark Identification Workshops and Safe Handling, Release, and Identification Workshops

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

ACTION: Notice of public workshops.

SUMMARY: Additional free Atlantic Shark Identification Workshops and Safe Handling, Release, and Identification Workshops will be held in August and September of 2020. Certain fishermen and shark dealers are required to attend a workshop to meet regulatory requirements and to maintain valid permits. Specifically, the Atlantic Shark Identification Workshop is mandatory for all federally permitted Atlantic shark dealers. The Safe Handling, Release, and Identification Workshop is mandatory for vessel owners and operators who use bottom longline, pelagic longline, or gillnet gear, and who have also been issued shark or swordfish limited access permits. More free workshops will be conducted during 2020 and will be announced in a future notice.

DATES: The additional Atlantic Shark Identification Workshops will be held on August 20, 2020, August 28, 2020, and September 3, 2020. The additional Safe Handling, Release, and Identification Workshops will be held on August 25, August 28, September 11, September 23, 2020, and September25, 2020. See **SUPPLEMENTARY INFORMATION** for further details.

ADDRESSES: The Atlantic Shark Identification Workshops will be held in Philadelphia, PA; Titusville, FL; and Boston, MA. The Safe Handling, Release, and Identification Workshops will be held in Philadelphia, PA; Gulfport, MS; Palm Coast, FL; and Charleston, SC. See **SUPPLEMENTARY INFORMATION** for further details on workshop locations.

FOR FURTHER INFORMATION CONTACT: Rick Pearson by email at *rick.a.pearson@noaa.gov,* or by phone at (727) 824–5399.

SUPPLEMENTARY INFORMATION: The workshop schedules, registration information, and a list of frequently asked questions regarding the Atlantic Shark Identification and Safe Handling, Release, and Identification workshops are posted on the internet at: *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/atlantic-shark-identification-workshops* and *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/safe-handling-release-and-identification-workshops.* The workshops announced in this notice are in addition to the rescheduled workshops announced in a previous notice (85 FR 33631, June 2, 2020) and other workshops for July through September of 2020 announced in a previous notice (85 FR 36565, June 17, 2020).

Atlantic Shark Identification Workshops

Since January 1, 2008, Atlantic shark dealers have been prohibited from receiving, purchasing, trading, or bartering for Atlantic sharks unless a valid Atlantic Shark Identification Workshop certificate is on the premises of each business listed under the shark dealer permit that first receives Atlantic sharks (71 FR 58057; October 2, 2006). Dealers who attend and successfully complete a workshop are issued a certificate for each place of business that is permitted to receive sharks. These certificate(s) are valid for 3 years. Thus, certificates that were initially issued in 2017 will be expiring in 2020. Approximately 170 free Atlantic Shark Identification Workshops have been conducted since July 2008.

Currently, permitted dealers may send a proxy to an Atlantic Shark Identification Workshop. However, if a dealer opts to send a proxy, the dealer must designate a proxy for each place of business covered by the dealer's permit that first receives Atlantic sharks. Only one certificate will be issued to each

proxy. A proxy must be a person who is currently employed by a place of business covered by the dealer's permit; is a primary participant in the identification, weighing, and/or first receipt of fish as they are offloaded from a vessel; and who fills out dealer reports. Atlantic shark dealers are prohibited from renewing a Federal shark dealer permit unless a valid Atlantic Shark Identification Workshop certificate for each business location that first receives Atlantic sharks has been submitted with the permit renewal application. Additionally, trucks or other conveyances that are extensions of a dealer's place of business must possess a copy of a valid dealer or proxy Atlantic Shark Identification Workshop certificate.

Workshop Dates, Times, and Locations

1. August 20, 2020, 12 p.m.–4 p.m., Hampton Inn, 8600 Bartram Avenue, Philadelphia, PA 19153.
2. August 28, 2020, 12 p.m.–4 p.m., Hampton Inn, 4760 Helen Hauser Boulevard, Titusville, FL 32780.
3. September 3, 2020, 12 p.m.–4 p.m., Embassy Suites, 207 Porter Street, Boston, MA 02128.

Registration

To register for a scheduled Atlantic Shark Identification Workshop, please contact Eric Sander at *ericssharkguide@yahoo.com* or at (386) 852–8588. Pre-registration is highly recommended, but not required.

Registration Materials

To ensure that workshop certificates are linked to the correct permits, participants will need to bring the following specific items to the workshop:

- Atlantic shark dealer permit holders must bring proof that the attendee is an owner or agent of the business (such as articles of incorporation), a copy of the applicable permit, and proof of identification.
- Atlantic shark dealer proxies must bring documentation from the permitted dealer acknowledging that the proxy is attending the workshop on behalf of the permitted Atlantic shark dealer for a specific business location, a copy of the appropriate valid permit, and proof of identification.

Workshop Objectives

The Atlantic Shark Identification Workshops are designed to reduce the number of unknown and improperly identified sharks reported in the dealer reporting form and increase the accuracy of species-specific dealer-reported information. Reducing the number of unknown and improperly identified sharks will improve quota monitoring and the data used in stock assessments. These workshops will train shark dealer permit holders or their proxies to properly identify Atlantic shark carcasses.

Safe Handling, Release, and Identification Workshops

Since January 1, 2007, shark limited-access and swordfish limited-access permit holders who fish with longline or gillnet gear have been required to submit a copy of their Safe Handling, Release, and Identification Workshop certificate in order to renew either permit (71 FR 58057; October 2, 2006). These certificate(s) are valid for 3 years. Certificates issued in 2017 will be expiring in 2020. As such, vessel owners who have not already attended a workshop and received a NMFS certificate, or vessel owners whose certificate(s) will expire prior to the next permit renewal, must attend a workshop to fish with, or renew, their swordfish and shark limited-access permits. Additionally, new shark and swordfish limited-access permit applicants who intend to fish with longline or gillnet gear must attend a Safe Handling, Release, and Identification Workshop and submit a copy of their workshop certificate before either of the permits will be issued. Approximately 350 free Safe Handling, Release, and Identification Workshops have been conducted since 2006.

In addition to certifying vessel owners, at least one operator on board vessels issued a limited-access swordfish or shark permit that uses longline or gillnet gear is required to attend a Safe Handling, Release, and Identification Workshop and receive a certificate. Vessels that have been issued a limited-access swordfish or shark permit and that use longline or gillnet gear may not fish unless both the vessel owner and operator have valid workshop certificates onboard at all times. Vessel operators who have not already attended a workshop and received a NMFS certificate, or vessel operators whose certificate(s) will expire prior to their next fishing trip, must attend a workshop to operate a vessel with swordfish and shark limited-access permits that uses longline or gillnet gear.

Workshop Dates, Times, and Locations

1. August 25, 2020, 9 a.m.–5 p.m., Embassy Suites, 9000 Bartram Avenue, Philadelphia, PA 19153.
2. August 28, 2020, 9 a.m.–5 p.m., Holiday Inn, 9515 Highway 49, Gulfport, MS 39503.
3. September 11, 2020, 9 a.m.–5 p.m., Hilton Garden Inn, 55 Town Center Boulevard, Palm Coast, FL 32164.
4. September 23, 2020, 9 a.m.–5 p.m., Hampton Inn, 678 Citadel Haven Drive, Charleston, SC 29414.
5. September 25, 2020, 9 a.m.–5 p.m., Holiday Inn, 300 Woodbury Avenue, Portsmouth, NH 03801.

Registration

To register for a scheduled Safe Handling, Release, and Identification Workshop, please contact Angler Conservation Education at (386) 682–0158. Pre-registration is highly recommended, but not required.

Registration Materials

To ensure that workshop certificates are linked to the correct permits, participants will need to bring the following specific items with them to the workshop:

- Individual vessel owners must bring a copy of the appropriate swordfish and/or shark permit(s), a copy of the vessel registration or documentation, and proof of identification.
- Representatives of a business-owned or co-owned vessel must bring proof that the individual is an agent of the business (such as articles of incorporation), a copy of the applicable swordfish and/or shark permit(s), and proof of identification.
- Vessel operators must bring proof of identification.

Workshop Objectives

The Safe Handling, Release, and Identification Workshops are designed to teach longline and gillnet fishermen the required techniques for the safe handling and release of entangled and/or hooked protected species, such as sea turtles, marine mammals, smalltooth sawfish, Atlantic sturgeon, and prohibited sharks. In an effort to improve reporting, the proper identification of protected species and prohibited sharks will also be taught at these workshops. Additionally, individuals attending these workshops will gain a better understanding of the requirements for participating in these fisheries. The overall goal of these workshops is to provide participants with the skills needed to reduce the mortality of protected species and prohibited sharks, which may prevent additional regulations on these fisheries in the future.

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

Dated: July 23, 2020.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–16385 Filed 7–28–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Responses to Office Action and Voluntary Amendment Forms

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), in accordance with the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651–0050 (Responses to Office Action and Voluntary Amendment Forms). The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

DATES: To ensure consideration, comments regarding this information collection must be received on or before September 28, 2020.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- *Email: InformationCollection@uspto.gov.* Include ''0651–0050 comment'' in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Kimberly Hardy, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Catherine Cain, Attorney Advisor, Office of the Commissioner for Trademarks, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450, by telephone at 571–272–8946, or by email at *Catherine.Cain@uspto.gov.* Additional information about this information collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

This collection of information is required by the Trademark Act (Act), 15 U.S.C. 1051 *et seq.,*[1] which provides for the Federal registration of trademarks, service marks, collective trademark and service marks, collective membership marks, and certification marks. Individuals and businesses that use such marks, or intend to use such marks, in interstate commerce may file an application to register their marks with the United States Patent and Trademark Office (USPTO). The USPTO also administers the Trademark Act through Title 37 of the Code of Federal Regulations. These regulations allow the USPTO to request and receive information required to process applications and allows applicants to submit certain amendments to their applications. This information collection includes information that was not submitted with the initial application and is needed by the USPTO to review applications for trademark registration.

In some cases, the USPTO issues Office Actions to applicants who have applied to register a mark, requesting information that was not provided with the initial submission, but is required before the issuance of a registration. Also, the USPTO may determine that a mark is not entitled to registration, pursuant to one or more provisions of the Trademark Act. In such cases, the USPTO will issue an Office Action advising the applicant of the refusal to register the mark. Applicants reply to these Office Actions by providing the required information and/or by putting forth legal arguments as to why the refusal of registration should be withdrawn.

Applicants may also supplement their applications and provide further information by filing a Voluntary Amendment Not in Response to USPTO Office Action/Letter, a Request for Reconsideration after Final Office Action, a Post-Approval/Publication/Post-Notice of Allowance (NOA) Amendment, a Petition to Amend Basis Post-Publication, or a Response to Suspension Inquiry or Letter of Suspension. In rare instances, an applicant may also submit a Substitute Trademark/Servicemark, Substitute Certification Mark, Substitute Collective Membership Mark, or Substitute Collective Trademark/Servicemark application.

[1] *https://www.uspto.gov/sites/default/files/trademarks/law/Trademark_Statutes.pdf.*

II. Method of Collection

Items in this information collection may be submitted via online electronic submissions. In limited circumstances, applicants may be permitted to submit the information in paper form by mail, fax, or hand delivery.

III. Data

OMB Control Number: 0651–0050.

Form Numbers:

- PTO–1957 (Response to Office Action)
- PTO–1960 (Request for Reconsideration After Final Office Action)
- PTO–1966 (Voluntary Amendment Not in Response to USPTO Office Action/Letter)
- PTO–1771 (Post-Approval/Publication/Post-Notice of Allowance (NOA) Amendment)
- PTO–1771 (Petition to Amend Basis Post-Publication)
- PTO–1822 (Response to Suspension Inquiry or Letter of Suspension)

Type of Review: Revision of a currently approved information collection.

Affected Public: Businesses or other for-profits; not-for-profit institutions; individuals and households.

Estimated Number of Respondents: 393,657 respondents per year.

Estimated Time per Response: The USPTO estimates that it will take the public between 15 minutes (0.25 hours) and 40 minutes (0.67 hours) to complete a response, depending on the complexity of the situation. This includes the time to gather the necessary information, prepare the appropriate documents, and submit the information to the USPTO.

Estimated Total Annual Respondent Burden Hours: 253,058 hours.

Estimated Total Annual Respondent Cost Burden: $101,223,200.

TABLE 1—TOTAL HOURLY BURDEN FOR PRIVATE SECTOR RESPONDENTS

Item No.	Item	Estimated annual respondents	Estimated annual responses (year) (a)	Estimated time for response (hours) (b)	Estimated annual burden (hour/year) (a) × (b) = (c)	Rate [2] ($/hour) (d)	Estimated annual burden (c) × (d) = (e)
1	Response to Office Action (TEAS)	275,180	275,179	0.67 (40 minutes)	184,370	$400	$73,748,000
2	Substitute Trademark/Servicemark Application, Principal Register (TEAS Global).	Same as line 1	2	0.50 (30 minutes)	1	400	400
3	Substitute Certification Mark (TEAS Global).	Same as line 1	2	0.50 (30 minutes)	1	400	400
4	Substitute Collective Membership Mark (TEAS Global).	Same as line 1	2	0.50 (30 minutes)	1	400	400
5	Substitute Collective Trademark/ Servicemark (TEAS Global).	Same as line 1	2	0.50 (30 minutes)	1	400	400
6	Voluntary Amendment Not in Response to USPTO Office Action/Letter (TEAS).	10,897	10,897	0.33 (25 minutes)	3,596	400	1,438,400
7	Request for Reconsideration After Final Office Action (TEAS).	15,762	15,762	0.67 (40 minutes)	10,561	400	4,224,400
8	Post-Approval/Publication/Post-Notice of Allowance (NOA) Amendment (TEAS).	3,498	3,498	0.42 (25 minutes)	1,469	400	587,600
9	Petition to Amend Basis Post-Publication (TEAS Global).	623	623	0.33 (25 minutes)	206	400	82,400
10	Response to Suspension Inquiry or Letter of Suspension (TEAS).	8,965	8,965	0.25 (15 minutes)	2,241	400	896,400
Totals		314,925	314,932		202,447		80,978,800

TABLE 2—TOTAL HOURLY BURDEN FOR INDIVIDUAL AND HOUSEHOLD RESPONDENTS

Item No.	Item	Estimated annual respondents	Estimated annual responses (year) (a)	Estimated time for response (hours) (b)	Estimated annual burden (hours/year) (c) (a) × (b) = (c)	Rate [3] ($/hour) (d)	Estimated annual burden (e) (c) × (d) = (e)
1	Response to Office Action (TEAS)	68,795	68,795	0.67 (40 minutes)	46,093	$400	$18,437,200
6	Voluntary Amendment Not in Response to USPTO Office Action/Letter (TEAS).	2,724	2,724	0.33 (25 minutes)	899	400	359,600
7	Request for Reconsideration After Final Office Action (TEAS).	3,941	3,941	0.67 (40 minutes)	2,640	400	1,056,000
8	Post-Approval/Publication/Post-Notice of Allowance (NOA) Amendment (TEAS).	875	875	0.42 (25 minutes)	368	400	147,200
9	Petition to Amend Basis Post-Publication (TEAS Global).	156	156	0.33 (25 minutes)	51	400	20,400
10	Response to Suspension Inquiry or Letter of Suspension (TEAS).	2,241	2,241	0.25 (15 minutes)	560	400	224,000
Totals		78,732	78,732		50,611		20,244,400

Estimated Total Annual Non-Hour Respondent Cost Burden: $99,440. There are no maintenance, operation, capital start-up, or recordkeeping costs associated with this information collection. However, this information collection does have annual non-hour costs in the form of postage costs and filing fees.

[2] 2019 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey.* The USPTO uses the mean rate for attorneys in private firms which is $400 per hour.

[3] 2019 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA);n *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey.* The USPTO uses the mean rate for attorneys in private firms which is $400 per hour.

TABLE 3—ANNUAL NON-HOUR COST BURDEN

Item No.	Item	Estimated annual responses (a)	Estimated cost ($) (b)	Estimated non-hour cost burden (a) × (b) = (c)
Filing Fees:				
1–5	Additional processing fee for application that does not meet TEAS Plus filing requirements, per Class.	172	$125.00	$21,500
9	Petition to Amend Basis Post-Publication (TEAS Global)	779	100.00	77,900
Postage Fees:				
1	Response to Office Action	5	8.05	40
Total	.....	.....	.....	99,440

Respondent's Obligation: Required to obtain or retain benefits.

IV. Request for Comments

The USPTO is soliciting public comments to:

(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 Agency's 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; and

(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.

All comments submitted in response to this notice are a matter of public record. USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personal identifying information in a comment, be aware that the entire comment— including personal identifying information—may be made publicly available at any time. While you may ask in your comment to withhold personal identifying information from public view, USPTO cannot guarantee that it will be able to do so.

Kimberly Hardy,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2020–16447 Filed 7–28–20; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0120]

Agency Information Collection Activities; Comment Request; Annual Progress Reporting Form for the American Indian Vocational Rehabilitation Services Program

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before September 28, 2020.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2020–SCC–0120. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact August Martin, 202–245–7410.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Annual Progress Reporting Form for the American Indian Vocational Rehabilitation Services Program.

OMB Control Number: 1820–0655.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local and Tribal Organizations.

Total Estimated Number of Annual Responses: 86.

Total Estimated Number of Annual Burden Hours: 817.

Abstract: The Rehabilitation Services Administration (RSA) of the U.S. Department of Education's (ED) Office of Special Education and Rehabilitative Services (OSERS) will use this data collection form to capture the performance data form grantees funded under the American Indian Vocational Rehabilitation Services (AIVRS) program (CFDA #84.250). RSA and ED will use the information gathered annually to: (a) Comply with reporting requirements under the Education Department General Administrative Regulations (EDGAR) 34 CFR part 75.118, (b) measure performance on the program in accordance with the program indicators identified in the Government Performance Result Act (GPRA), and (c) provide information annually to Congress on activities conducted under this program.

The proposed changes to the existing form will improve user friendliness, clarity of data element questions, and accuracy of data reported. These revisions are not significantly different from the original collection, but are proposed to provide clarity, consistency, and usability. In order to improve the user friendliness of the form, some sections were reorganized to enhance the natural flow of data collection. Data element questions were revised to improve clarity of the requests, which will result in accuracy of data being reported. On additional data element was inserted in order to ensure grantees remain compliant with regulatory requirements, but the additional data element is offset by the elimination and consolidation of other sections in this ICR. Additionally, ED had revised how it will collect survey data regarding the Training and Technical Needs of AIVRS projects and the entire section of the report is deleted to further reduces burden. The Training and Technical Needs assessment survey will not be conducted independent of the ICR.

Dated: July 23, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–16353 Filed 7–28–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0124]

Agency Information Collection Activities; Comment Request; Education Stabilization Fund—Elementary and Secondary School Emergency Relief Fund (ESSER) Recipient Data Collection Form

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before September 28, 2020.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2020–SCC–0124. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance, Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Gabriella Tanner, 202–453–6129, or email *esserf@ed.gov.*

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Education Stabilization Fund—Elementary and Secondary School Emergency Relief Fund (ESSER) Recipient Data Collection Form.

OMB Control Number: 1810–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local and Tribal Organizations.

Total Estimated Number of Annual Responses: 14,656.

Total Estimated Number of Annual Burden Hours: 44,248.

Abstract: This information collection supports the annual collection of data pertaining to the uses of funds under the Elementary and Secondary School Emergency Relief Fund (ESSER Fund). The Department ESSER awards grants to State educational agencies (SEAs) and analogous grants to Outlying Areas for the purpose of providing local educational agencies (LEAs), including charter schools that are LEAs, with emergency relief funds to address the impact that Novel Coronavirus Disease 2019 (COVID–19) has had, and continues to have, on elementary and secondary schools across the nation. LEAs must provide equitable services to students and teachers in non-public schools as required under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The information will be reviewed by Department employees to ensure that ESSER funds are used in accordance with Sec. 18003(d) of the CARES Act and will be shared with the public to promote transparency regarding the allocation and uses of funds.

ESSER Reporting Requirements: Data collected through this information

collection will inform Department monitoring and oversight, and public reporting and is in addition to reporting already required under the Federal Funding Accountability and Transparency Act of 2006 (FFATA), Public Law 109–282, as amended by the Digital Accountability and Transparency Act (DATA Act), Public Law 113–101.

ESSER Reporting Timeframe: The anticipated reporting periods and associated deadlines for this information collection are as follows:

The First Annual Report is due on January 29, 2021 and applies to the reporting period from March 13, 2020 through September 30, 2020. The Second Annual Report is due on January 31, 2022 and applies to the reporting period from October 1, 2020 through September 30, 2021. The Third Annual Report is due on March 1, 2023 and applies to the reporting period from October 1, 2021 through December 31, 2022.

Directed Questions: The Department requests input from data submitters and stakeholders on the following directed questions. Please note that in addition to these questions, public comments are encouraged on all of the changes proposed. While these questions are directed to SEA data submitters, comments from all stakeholders on these topics are welcome.

(1) What data in this form will be difficult to collect or report and why? Are there changes that could be made to improve the quality of the data or reduce the burden? What are the overall challenges to reporting these data on an annual basis?

(2) The Department is interested in reducing the burden of data collection and making use of existing data when at all possible. For example, are the proposed data on LEAs available in State data systems? If data are not available in the State data system, is it feasible for States to collect these data from LEAs that received ESSER funding?

(3) Are the proposed data on student participation and engagement during remote learning currently being tracked by LEAs or SEAs? Are the proposed methods to document student participation and engagement during remote learning reliable? Are there additional methods used by LEAs to document student participation and engagement during remote learning?

(4) Are SEAs and LEAs able determine to what proportion of students within the LEA had internet access (school or family provided internet access) at home?

(5) Will the proposed method for collecting the number of FTE positions created or retained as a result of ESSER funds awarded to the SEA yield accurate data? Is there an alternative methodology that would improve the accuracy of the data?

(6) What changes should be made to the form to accommodate data collection from the Outlying Areas of the United States, specifically: The US Virgin Islands (VI), Guam (GU), the Commonwealth of the Northern Mariana Islands (CNMI), and American Samoa (AS)?

Dated: July 24, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–16445 Filed 7–28–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Education Innovation and Research (EIR) Program—Early-Phase Grants

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

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2020 for the EIR program—Early-phase Grants, Catalog of Federal Domestic Assistance (CFDA) number 84.411C (Early-phase Grants). This notice relates to the approved information collection under OMB control number 1855–0021.

DATES:

Applications Available: July 31, 2020.

Deadline for Notice of Intent to Apply: August 18, 2020.

Deadline for Transmittal of Applications: September 10, 2020.

Deadline for Intergovernmental Review: November 10, 2020.

Pre-Application Information: The Department will post additional competition information for prospective applicants on the EIR program website: *https://oese.ed.gov/offices/office-of-discretionary-grants-support-services/innovation-early-learning/education-innovation-and-research-eir/fy-2020-competition-2/.*

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.*

FOR FURTHER INFORMATION CONTACT: Ashley Brizzo, U.S. Department of Education, 400 Maryland Avenue SW, Room 3E325, Washington, DC 20202–5900. Telephone: (202) 453–7122. Email: *eir@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The EIR program, established under section 4611 of the Elementary and Secondary Education Act, as amended (ESEA), provides funding to create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based, field-initiated innovations to improve student achievement and attainment for high-need students; and rigorously evaluate such innovations. The EIR program is designed to generate and validate solutions to persistent education challenges and to support the expansion of those solutions to serve substantially larger numbers of students.

The central design element of the EIR program is its multi-tier structure that links the amount of funding an applicant may receive to the quality of the evidence supporting the efficacy of the proposed project, with the expectation that projects that build this evidence will advance through EIR's grant tiers: ''Early-phase,'' ''Mid-phase,'' and ''Expansion.'' Applicants proposing innovative practices that are supported by limited evidence can receive relatively small grants to support the development, implementation, and initial evaluation of the practices; applicants proposing practices supported by evidence from rigorous evaluations, such as an experimental study (as defined in this notice), can receive larger grant awards to support expansion across the country. This structure provides incentives for applicants to—(1) explore new ways of addressing persistent challenges that other educators can build on and learn from; (2) build evidence of effectiveness of their practices; and (3) replicate and scale successful practices in new schools, districts, and States while addressing the barriers to scale, such as cost structures and implementation fidelity.

All EIR projects are expected to generate information regarding their effectiveness in order to inform EIR grantees' efforts to learn about and improve upon their efforts, and to help similar, non-EIR efforts across the country benefit from EIR grantees' knowledge. By requiring that all grantees conduct independent evaluations of their EIR projects, EIR ensures that its funded projects make a significant contribution to improving the quality and quantity of information available to practitioners and policymakers about which practices improve student achievement and attainment, for which types of students, and in what contexts.

In prior years, the Department has awarded three types of grants under this program: ''Early-phase'' grants, ''Mid-phase'' grants, and ''Expansion'' grants. For FY 2020, the Department will award two types of grants: ''Early-phase'' grants and ''Mid-phase'' grants. These grants differ in terms of the level of prior evidence of effectiveness required for consideration for funding, the expectations regarding the kind of evidence and information funded projects should produce, the level of scale funded projects should reach, and, consequently, the amount of funding available to support each type of project.

The Department expects that Early-phase grants provide funding to support the development, implementation, and feasibility testing of a program, which prior research suggests has promise, for the purpose of determining whether the program can successfully improve student achievement and attainment for high need students. Early-phase grants must demonstrate a rationale. These Early-phase grants are not intended simply to implement established practices in additional locations or address needs that are unique to one particular context. The goal is to determine whether and in what ways relatively newer practices can improve student achievement and attainment for high need students.

The notice inviting applications for Mid-phase grants was published in the **Federal Register** on April 10, 2020 (85 FR 20254), available at *www.federalregister.gov/d/2020-07556;* applications for that competition were due on June 15, 2020.

Background:

The premise of the EIR program is that new and innovative programs and practices can help to solve the persistent problems in education that prevent students, particularly high-need students, from succeeding. These innovations need to be evaluated, and, if sufficient evidence of effectiveness can be demonstrated, the intent is for these innovations to be replicated and tested in new populations and settings. EIR is not intended to provide support for practices that are already commonly implemented by educators, unless significant adaptations of such practices warrant testing to determine if they can accelerate achievement, or greatly increase the efficiency and likelihood that they can be widely implemented in a variety of new populations and settings effectively.

As an EIR project is implemented, grantees are encouraged to learn more about how the practices improve student achievement and attainment; and to develop increasingly rigorous evidence of effectiveness and new strategies to efficiently and cost-effectively scale to new school districts, regions, and States. Applicants must develop a logic model (as defined in this notice) that includes the goals, objectives, proposed outcomes, and key project components (as defined in this notice) of the project.

Disseminating evaluation findings is a critical element of every project, even if a rigorous evaluation does not demonstrate positive results. Such results can influence the next stage of education practice and promote follow-up studies that build upon the results. The EIR program considers all high-quality evaluations to be a valuable contribution to the field of education research and encourages the documentation and sharing of lessons learned.

For those innovations that have positive results and have the potential for continued development and implementation, the Department is interested in learning more about continued efforts regarding cost-effectiveness and feasibility when scaled to additional populations and settings. EIR projects at the Mid-phase level are encouraged to test new strategies for recruiting and supporting new project adoption, seek efficiencies where project implementation has been too costly or cumbersome to operate at scale, and test new ways of overcoming any other barriers in practice or policy that might inhibit project growth. Early-phase grantees that are not yet ready to scale are still encouraged to think about how their innovations might translate to other populations or settings in the long term and to select their partners and implementation sites accordingly.

All EIR applicants and grantees should also consider how they need to develop their organizational capacity, project financing, or business plans to sustain their projects and continue implementation and adaptation after Federal funding ends. The Department intends to provide grantees with technical assistance in their dissemination, scaling, and sustainability efforts.

EIR is designed to offer opportunities for States, districts, schools, and educators to develop innovations and scale effective practices that address their most pressing challenges. Early-phase grantees are encouraged to make continuous improvements in project design and implementation before conducting a full-scale evaluation of effectiveness. Grantees should consider how easily others could implement the proposed practice, and how its implementation could potentially be improved. Additionally, grantees should consider using data from early indicators to gauge initial impact and to consider possible changes in implementation that could increase student achievement and attainment.

By focusing on continuous improvement and iterative development, Early-phase grantees can make adaptations that are necessary to increase their practice's potential to be effective and ensure that the EIR-funded evaluation assesses the impact of a thoroughly conceived practice.

Early-phase applicants should develop, implement, and test the feasibility of their projects. The evaluation of an Early-phase project should be an experimental or quasi-experimental design study (as defined in this notice) that can determine whether the program can successfully improve student achievement and attainment for high-need students. Early-phase grantees' evaluation designs are encouraged to have the potential to demonstrate a statistically significant effect on improving student outcomes or other relevant outcomes based on moderate evidence (as defined in this notice) from at least one well-designed and well-implemented experimental study. The Department intends to provide grantees and their independent evaluators with evaluation technical assistance. This evaluation technical assistance could include grantees and their independent evaluators providing to the Department or its contractor updated comprehensive evaluation plans in a format as requested by the technical assistance provider and using such tools as the Department may request. Grantees will be encouraged to update this evaluation plan at least annually to reflect any changes to the evaluation, with updates consistent with the scope and objectives of the approved application.

The FY 2020 Early-phase competition includes three absolute priorities and

two competitive preference priorities. All Early-phase applicants must address Absolute Priority 1. Early-phase applicants are also required to address one of the other two absolute priorities. Applicants addressing Absolute Priority 2 also have the option to address Competitive Preference Priority 1. Applicants addressing Absolute Priority 3 have the option to address Competitive Preference Priority 2. The absolute priorities and the competitive preference priorities align with the purpose of the program and the Administration's priorities.

Absolute Priority 1—Demonstrates a Rationale, establishes the evidence requirement for this tier of grants. All Early-phase applicants must submit prior evidence of effectiveness that meets the demonstrates a rationale (as defined in this notice) evidence standard.

Absolute Priority 2—Field-Initiated Innovations—STEM, is intended to highlight the Administration's efforts to ensure our Nation's economic competitiveness by improving and expanding STEM learning and engagement, including computer science (as defined in this notice).

In Absolute Priority 2, the Department recognizes the importance of funding Pre-Kindergarten (Pre-K) through grade 12 STEM education and anticipates that projects would expand opportunities for high-need students. Within this absolute priority, the Department includes Competitive Preference Priority 1, which specifically focuses on expanding opportunities in computer science for underserved populations such as minorities, girls, and youth from rural communities and low-income families, to help reduce achievement and attainment gaps in a manner consistent with nondiscrimination requirements contained in the U.S. Constitution and Federal civil rights laws.

Absolute Priority 3—Teacher-Directed Professional Learning—is intended to support efforts to develop, implement, and evaluate teacher-directed professional learning projects designed to enhance instructional practice and improve achievement and attainment for high-need students. The Department believes that teacher-directed professional development provided through such projects may be more effective in improving instructional practice and student outcomes than the one-size-fits-all professional development activities often funded by school systems in response to districtwide improvement goals.

In Absolute Priority 3, the Department identifies a need for innovative projects that develop and test approaches providing teachers with professional learning stipends. With the autonomy to identify instructionally relevant professional learning, teachers can improve their craft to better support student achievement and attainment for high-need students. Within this absolute priority, the Department includes Competitive Preference Priority 2, which encourages partnerships between an eligibly entity and a State educational agency (SEA).

Through these priorities, the Department intends to advance innovation, build evidence, and address the learning and achievement of high-need students beginning in Pre-K through grade 12.

Priorities: This notice includes three absolute priorities and two competitive preference priorities. In accordance with 34 CFR 75.105(b)(2)(ii), Absolute Priority 1 is from the notice of final priorities published in the **Federal Register** on March 9, 2020 (85 FR 13640) (Administrative Priorities). In accordance with 34 CFR 75.105(b)(2)(iv), Absolute Priority 2 is from section 4611(a)(1)(A) of the ESEA and the Secretary's Final Supplemental Priorities and Definitions for Discretionary Grant Programs (Supplemental Priorities) published in the **Federal Register** on March 2, 2018 (83 FR 9096). Competitive Preference Priority 1 is from the Supplemental Priorities. Absolute Priority 3 and Competitive Preference Priority 2 are from the Department's notice of final priorities, requirements, definition, and selection criteria published elsewhere in this issue of the **Federal Register** (NFP).

In the Early-phase grant competition, Absolute Priorities 2 and 3 constitute their own funding categories. The Secretary intends to award grants under both of these absolute priorities provided that applications of sufficient quality are submitted. To ensure that applicants are considered for the correct type of grant, applicants must clearly identify the specific absolute priority that the proposed project addresses. If an entity is interested in proposing two separate projects (one that addresses Absolute Priority 2 and another that addresses Absolute Priority 3), separate applications must be submitted.

Absolute Priorities: For FY 2020 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider only applications that meet Absolute Priority 1—Demonstrates a Rationale, and one additional absolute priority (either Absolute Priority 2 or Absolute Priority 3).

These priorities are:

Absolute Priority 1—Applications that Demonstrate a Rationale.

Under this priority, an applicant proposes a project that demonstrates a rationale (as defined in 34 CFR 77.1).

Absolute Priority 2—Field-Initiated Innovations—Promoting STEM Education, With a Particular Focus on Computer Science.

Under the priority, we provide funding to projects that are designed to—

(1) Create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based (as defined in this notice), field-initiated innovations to improve student achievement and attainment for high-need students; and

(2) Improve student achievement or other educational outcomes in one or more of the following areas: Science, technology, engineering, math, or computer science.

Absolute Priority 3—Teacher Directed Professional Learning.

Under this priority, an applicant must propose a project in which classroom teachers receive stipends to select professional learning alternatives that are instructionally relevant and meet their individual needs related to instructional practices for high-need students. Additionally, teachers receiving stipends must be allowed the flexibility to replace a significant portion (no less than 20 percent) of existing mandatory professional development with such teacher-directed learning, which must also be allowed to fully count toward any mandatory teacher professional development goals (*e.g.,* professional development hours required as part of certification renewal, designated professional days mandated by districts).

Competitive Preference Priorities: For FY 2020 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i) we award up to an additional five points to an application, depending on how well the application addresses the applicable competitive preference priority. Within Absolute Priority 2, we give competitive preference to applications that address Competitive Preference Priority 1. Within Absolute Priority 3, we give competitive preference to applications that address Competitive Preference Priority 2.

These priorities are:

Competitive Preference Priority 1—Computer Science (up to 5 Points).

Projects designed to improve student achievement or other educational outcomes in computer science (as defined in this notice). These projects must address the following priority area: Expanding access to and participation in rigorous computer science coursework for traditionally underrepresented students such as racial or ethnic minorities, women, students in communities served by rural local educational agencies (as defined in this notice), children or students with disabilities (as defined in this notice), or low-income individuals (as defined under section 312(g) of the Higher Education Act of 1965, as amended).

Competitive Preference Priority 2—State Educational Agency Partnership (up to 5 points).

Under this priority, an applicant must demonstrate it has established a partnership between an eligible entity and an SEA (with either member of the partnership serving as the applicant) to support the proposed project.

Application Requirements: There are no application requirements for applicants that address Absolute Priority 2. For FY 2020, and any subsequent year in which we make awards from the list of unfunded applications from this competition, applicants that address Absolute Priority 3 must meet the following application requirements from the NFP.

An applicant must—

(a) Describe the pool of teachers eligible to request a stipend, including whether the applicant intends to prioritize eligibility based on content areas, strategic staffing initiatives, or other factors (and including a rationale for how such a determination addresses the needs of high-need students, as defined by the applicant);

(b) Describe the anticipated level of teacher participation, including—

(1) Current information on teacher satisfaction with existing professional learning;

(2) Details on the planned outreach strategy to communicate the stipend opportunity to eligible teachers;

(3) A summary of the ways in which teachers were involved in developing the proposed project; and

(4) A plan for how to include teachers in key decisions about the stipend system.

(c) Describe the proposed stipend structure, including—

(1) Estimated dollar amount per stipend, including associated expenses related to the professional learning (*e.g.,* materials, transportation, etc.);

(2) A rationale for how the estimated dollar amount per stipend is sufficient to ensure access to professional learning activities that are, at minimum, comparable in quality, frequency, and duration to the professional development other non-participating teachers will receive in a given year;

(3) Mechanisms to protect against fraud, waste, and abuse (*e.g.,* monitoring systems, reviews for conflicts of interest); and

(4) Plans for how the applicant will select participants if there is more interest than available stipends (*e.g.,* prioritizing by student need or teacher need, content area, human capital priorities, rubric-based review of requests, lottery);

(d) Describe details about the stipend system, including—

(1) How the applicant will update its policies to offer stipends to teachers such that a significant portion (no less than 20 percent) of existing mandatory professional development is replaced by teacher-directed professional learning, including—

(i) The professional development days or activities from which participating teachers will be released in order to enable teacher-directed learning opportunities and to ensure that teacher-directed learning replaces a significant portion of existing mandatory professional development; or

(ii) Other methods in which participating teachers will be given the flexibility to participate in teacher-directed learning (*e.g.,* by providing release from and substitute teacher coverage during regular instructional days) and how such methods will also ensure participating teachers are released from a significant portion of existing professional development requirements;

(2) How the applicant will ensure that teacher-directed learning will fully substitute for mandatory professional development in meeting mandatory professional development goals or activities (*e.g.,* professional development hours required as part of certification renewal, district- or contract-required professional development hours);

(3) How the applicant will provide information to teachers about professional learning options not previously available to teachers (*e.g.,* list of innovative options, qualified providers, other resources); and

(4) In addition to any list of professional learning options or providers identified by the applicant, mechanisms for teachers to independently select different high-quality, instructionally relevant professional learning activities connected to the achievement and attainment of high-need students (based on teacher-identified needs such as self-assessment surveys, student assessment data, and professional growth plans);

(e) Describe strategies for supporting teachers' implementation of changes in instructional practice as a result of their professional learning;

(f) Describe the process for managing the stipend system, including—

(1) For professional learning options that are among a list of options identified by the applicant: The processes for teachers to submit their requests to participate in those options in place of a previously required training and the processes for direct vendor payment using the stipend; and

(2) For professional learning options selected by a teacher that are not on the applicant's list of options: How the applicant will determine that the activity meets the definition of ''professional learning'' and is reasonable, and what processes the applicant will implement to ensure payment or timely reimbursement to teachers;

(g) Describe the proposed strategy to expand the use of professional learning stipends (pending the results of the evaluation), including—

(1) Plans for continuously improving the stipend system in order to, over time, offer more teachers the opportunity to engage in teacher-directed professional learning and, for participating teachers, ensure a higher percentage of all mandatory professional learning is teacher-directed; and

(2) Mechanisms for incorporating effective practices discovered through teacher-directed professional learning into the professional development curriculum for all teachers; and

(h) Provide an assurance that—

(1) At a minimum, the SEA or local educational agency (LEA) involved in the project (as an applicant, partner, or implementation site) will maintain its current fiscal and administrative levels of effort in teacher professional development and allow the professional learning activities funded through the stipends to supplement the level of effort that is typically supported by the applicant;

(2) Project funds will only be used for instructionally relevant professional learning activities and not solely for obtaining advanced degrees, taking or preparing for licensure exams, or for pursuing personal enrichment activities; and

(3) Projects will allow for a variety professional learning options for teachers and not limit use of the stipend to an overly restrictive set of choices (for example, professional learning provided only by the applicant or partners,

specific pedagogical or philosophical viewpoints, or organizations with specific methodological stances). The applicant and any application partners will not be the primary financial beneficiaries of the professional learning stipends, and there is no conflict between the applicant, any application partner, and the purpose of providing teachers the autonomy to select their own professional learning opportunities.

Definitions: The definitions of ''baseline,'' ''demonstrates a rationale,'' ''experimental study,'' ''logic model,'' ''moderate evidence,'' ''nonprofit,'' ''performance measure,'' ''performance target,'' ''project component,'' ''quasi-experimental design study,'' ''relevant outcome,'' and ''What Works Clearinghouse Handbook (WWC Handbook)'' are from 34 CFR 77.1. The definitions of ''children or students with disabilities,'' ''computer science,'' and ''rural local educational agency'' are from the Supplemental Priorities. The definitions of ''evidence-based,'' ''local educational agency,'' and ''State educational agency'' are from section 8101 of the ESEA. The definition of ''professional learning'' is from the Department's NFP.

Baseline means the starting point from which performance is measured and targets are set.

Children or students with disabilities means children with disabilities as defined in the Individuals with Disabilities Education Act (IDEA) or individuals defined as having a disability under Section 504 of the Rehabilitation Act of 1973 (Section 504)(or children or students who are eligible under both laws).

Computer science means the study of computers and algorithmic processes and includes the study of computing principles and theories, computational thinking, computer hardware, software design, coding, analytics, and computer applications.

Computer science often includes computer programming or coding as a tool to create software, including applications, games, websites, and tools to manage or manipulate data; or development and management of computer hardware and the other electronics related to sharing, securing, and using digital information.

In addition to coding, the expanding field of computer science emphasizes computational thinking and interdisciplinary problem-solving to equip students with the skills and abilities necessary to apply computation in our digital world.

Computer science does not include using a computer for everyday activities, such as browsing the internet; use of tools like word processing, spreadsheets, or presentation software; or using computers in the study and exploration of unrelated subjects.

Demonstrates a rationale means a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

Evidence-based means an activity, strategy, or intervention that demonstrates a rationale based on high quality research findings or positive evaluation that such activity, strategy, or intervention is likely to improve student outcomes or other relevant outcomes.

Experimental study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbook:

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment.

Local educational agency (LEA) means:

(a) In General. A public board of education or other public authority legally constituted within a State for either administrative control or direction of, or to perform a service function for, public elementary schools or secondary schools in a city, county, township, school district, or other political subdivision of a State, or of or for a combination of school districts or counties that is recognized in a State as an administrative agency for its public elementary schools or secondary schools.

(b) Administrative Control and Direction. The term includes any other public institution or agency having administrative control and direction of a public elementary school or secondary school.

(c) Bureau of Indian Education Schools. The term includes an elementary school or secondary school funded by the Bureau of Indian Education but only to the extent that including the school makes the school eligible for programs for which specific eligibility is not provided to the school in another provision of law and the school does not have a student population that is smaller than the student population of the local educational agency receiving assistance under the ESEA with the smallest student population, except that the school shall not be subject to the jurisdiction of any SEA (as defined in this notice) other than the Bureau of Indian Education.

(d) Educational Service Agencies. The term includes educational service agencies and consortia of those agencies.

(e) State Educational Agency. The term includes the SEA in a State in which the SEA is the sole educational agency for all public schools.

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Moderate evidence means that there is evidence of effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations or settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1 or 3.0 of the WWC Handbook reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1 or 3.0 of the WWC Handbook reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome based on

a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study or quasi-experimental design study reviewed and reported by the WWC using version 2.1 or 3.0 of the WWC Handbook, or otherwise assessed by the Department using version 3.0 of the WWC Handbook, as appropriate, and that—

(A) Meets WWC standards with or without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1, or 3.0 of the WWC Handbook; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy this requirement.

Nonprofit, as applied to an agency, organization, or institution, means that it is owned and operated by one or more corporations or associations whose net earnings do not benefit, and cannot lawfully benefit, any private shareholder or entity.

Performance measure means any quantitative indicator, statistic, or metric used to gauge program or project performance.

Performance target means a level of performance that an applicant would seek to meet during the course of a project or as a result of a project.

Professional learning means instructionally relevant activities to improve and increase classroom teachers'—

(1) Content knowledge;

(2) Understanding of instructional strategies and intervention techniques for high-need students, including how best to analyze and use data to inform such strategies and techniques; and

(3) Classroom management skills to better support high-need students.

Professional learning must be job-embedded or classroom-focused, collaborative, data-driven, part of a sustained and intensive program, and related to the achievement and attainment of high-need students. Professional learning may include innovative activities such as peer shadowing opportunities, virtual mentoring, online modules, professional learning communities, communities of practice, action research, micro-credentials, and coaching support.

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Quasi-experimental design study means a study using a design that attempts to approximate an experimental study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.,* establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbook.

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program.

Rural local educational agency means a local educational agency that is eligible under the Small Rural School Achievement (SRSA) program or the Rural and Low-Income School (RLIS) program authorized under Title V, Part B of the ESEA. Eligible applicants may determine whether a particular district is eligible for these programs by referring to information on the Department's website at *www2.ed.gov/nclb/freedom/local/reap.html.*

State educational agency (SEA) means the agency primarily responsible for the State supervision of public elementary schools and secondary schools.

What Works Clearinghouse Handbook (WWC Handbook) means the standards and procedures set forth in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (incorporated by reference, see 34 CFR 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the Handbook documentation.

Note: The What Works Clearinghouse Procedures and Standards Handbook (Version 3.0), as well as the more recent What Works Clearinghouse Handbooks released in October 2017 (Version 4.0) and January 2020 (Version 4.1), are available at *https://ies.ed.gov/ncee/wwc/Handbooks.*

Authority: Section 4611 of the ESEA, 20 U.S.C. 7261.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The Administrative Priorities. (e) The Supplemental Priorities. (f) The NFP.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $178,600,000.

These estimated available funds are the total available for both Early-phase and Mid-phase grants. Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards for Absolute Priority 2: $3,000,000–$4,000,000.

Estimated Average Size of Awards for Absolute Priority 2: $4,000,000.

Maximum Award for Absolute Priority 2: We will not make an award exceeding $4,000,000 for a project period of 60 months.

Estimated Number of Awards for Absolute Priority 2: 5–9.

Estimated Range of Awards for Absolute Priority 3: $8,000,000–$12,000,000.

Estimated Average Size of Awards for Absolute Priority 3: $10,000,000.

Maximum Award for Absolute Priority 3: We will not make an award exceeding $12,000,000 for a project period of 60 months.

Estimated Number of Awards for Absolute Priority 3: 6–8.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months. We anticipate that initial awards under this competition will be made for a three-year (36-month) period.

Contingent upon the availability of funds and each grantee's substantial progress towards accomplishing the goals and objectives of the project as described in its approved application, we may make continuation awards to grantees for the remainder of the project period.

Applicants must propose a budget that covers the entire project period of up to 60 months.

Note: Under section 4611(c) of the ESEA, the Department must use at least 25 percent of EIR funds for a fiscal year to make awards to applicants serving rural areas, contingent on receipt of a sufficient number of applications of sufficient quality. For purposes of this competition, we will consider an applicant as rural if the applicant meets the qualifications for rural applicants as described in the *Eligible Applicants* section and the applicant certifies that it meets those qualifications through the application.

In implementing this statutory provision and program requirement, the Department may fund high-quality applications from rural applicants and applications submitted under Absolute Priorities 2 and 3 out of rank order in the Early-phase competition.

In addition, for FY 2020 Early-phase competition, the Department intends to award an estimated $34 million in funds for STEM projects, contingent on receipt of a sufficient number of applications of sufficient quality.

III. Eligibility Information

1. *Eligible Applicants:*

(a) An LEA;

(b) An SEA;

(c) The Bureau of Indian Education (BIE);

(d) A consortium of SEAs or LEAs;

(e) A nonprofit organization; and

(f) An LEA, an SEA, the BIE, or a consortium described in clause (d), in partnership with—

(1) A nonprofit organization;

(2) A business;

(3) An educational service agency; or

(4) An IHE.

To qualify as a rural applicant under the EIR program, an applicant must meet both of the following requirements:

(a) The applicant is—

(1) An LEA with an urban-centric district locale code of 32, 33, 41, 42, or 43, as determined by the Secretary;

(2) A consortium of such LEAs;

(3) An educational service agency or a nonprofit organization in partnership with such an LEA; or

(4) A grantee described in clause (1) or (2) in partnership with an SEA; and

(b) A majority of the schools to be served by the program are designated with a locale code of 32, 33, 41, 42, or 43, or a combination of such codes, as determined by the Secretary.

Applicants are encouraged to retrieve locale codes from the National Center for Education Statistics School District search tool (*https://nces.ed.gov/ccd/districtsearch/*), where districts can be looked up individually to retrieve locale codes, and Public School search tool (*https://nces.ed.gov/ccd/schoolsearch/*), where individual schools can be looked up to retrieve locale codes. More information on rural applicant eligibility is in the application package.

If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing: (1) Proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code, (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual, (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant, or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate. In addition, any IHE is eligible to be a partner in an application where an LEA, SEA, BIE, consortium of SEAs or LEAs, or a nonprofit organization is the lead applicant that submits the application. A nonprofit organization, such as a development foundation, that is affiliated with a public IHE can apply for a grant. A public IHE that has 501(c)(3) status would also qualify as a nonprofit organization and could be a lead applicant for an EIR grant. A public IHE without 501(c)(3) status, or that could not provide any other documentation described in 34 CFR 75.51(b), however, would not qualify as a nonprofit organization, and therefore could not apply for and receive an EIR grant.

2. *Cost Sharing or Matching:* Under section 4611(d) of the ESEA, each grant recipient must provide, from Federal, State, local, or private sources, an amount equal to 10 percent of funds provided under the grant, which may be provided in cash or through in-kind contributions, to carry out activities supported by the grant. Grantees must include a budget showing their matching contributions to the budget amount of EIR grant funds and must provide evidence of their matching contributions for the first year of the grant in their grant applications. Section 4611(d) of the ESEA also authorizes the Secretary to waive this matching requirement on a case-by-case basis, upon a showing of exceptional circumstances, such as:

(a) The difficulty of raising matching funds for a program to serve a rural area;

(b) The difficulty of raising matching funds in areas with a concentration of LEAs or schools with a high percentage of students aged 5 through 17—

(1) Who are in poverty, as counted in the most recent census data approved by the Secretary;

(2) Who are eligible for a free or reduced price lunch under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 *et seq.*);

(3) Whose families receive assistance under the State program funded under part A of title IV of the Social Security Act (42 U.S.C. 601 *et seq.*); or

(4) Who are eligible to receive medical assistance under the Medicaid program; and

(c) The difficulty of raising funds on Tribal land.

Applicants that wish to apply for a waiver must include a request in their application that describes why the matching requirement would cause serious hardship or an inability to carry out project activities. Further information about applying for waivers can be found in the application package. However, given the importance of matching funds to the long-term success of the project, the Secretary expects eligible entities to identify appropriate matching funds.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

4. *Other:* a. *Funding Categories:* An applicant will be considered for an award only for the type of EIR grant for which it applies (*i.e.,* Early-phase: Absolute Priority 2 or Early-phase: Absolute Priority 3). An applicant may not submit an application for the same proposed project under more than one type of grant (*e.g.,* both an Early-phase grant and Mid-phase grant).

Note: Each application will be reviewed under the competition it was submitted under in the *Grants.gov* system, and only applications that are successfully submitted by the established deadline will be peer reviewed. Applicants should be careful that they download the intended EIR application package and that they submit their applications under the intended EIR competition.

b. *Evaluation:* The grantee must conduct an independent evaluation of the effectiveness of its project.

c. *High-need students:* The grantee must serve high-need students.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf,* which contain requirements and information on how to submit an application.

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for Early-phase grants, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative for an Early-phase grant to no more than 25 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative.

6. *Notice of Intent to Apply:* We will be able to develop a more efficient process for reviewing grant applications if we know the approximate number of applicants that intend to apply for funding under this competition. Therefore, the Secretary strongly encourages each potential applicant to notify us of the applicant's intent to apply by completing a web-based form. When completing this form, applicants will provide (1) the applicant organization's name and address and (2) which absolute priority the applicant intends to address. Applicants may access this form using the link available on the Notice of Intent to Apply section of the competition website: *https://oese.ed.gov/offices/office-of-discretionary-grants-support-services/innovation-early-learning/education-innovation-and-research-eir/fy-2020-competition-2/.* Applicants that do not complete this form may still submit an application.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for Absolute Priority 2 are from 34 CFR 75.210. The selection criteria for Absolute Priority 3 are from 34 CFR 75.210 and the NFP. The points assigned to each criterion are indicated in the parentheses next to the criterion. An applicant may earn up to a total of 100 points based on the selection criteria for the application.

In evaluating an application for Absolute Priority 2, the Secretary considers the following criteria:

A. *Quality of the Project Design (up to 40 points).*

The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(1) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable. (10 points)

(2) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs. (10 points)

(3) The extent to which the design of the proposed project reflects up-to-date knowledge from research and effective practice. (10 points)

(4) The potential contribution of the proposed project to increased knowledge or understanding of educational problems, issues, or effective strategies. (10 points)

B. *Adequacy of Resources and Quality of the Management Plan (up to 35 points).*

The Secretary considers the adequacy of resources and the quality of the management plan for the proposed project. In determining the adequacy of resources and quality of the management plan for the proposed project, the Secretary considers the following factors:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks. (10 points)

(2) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project. (5 points)

(3) The qualifications, including relevant training and experience, of key project personnel. (5 points)

(4) The adequacy of procedures for ensuring feedback and continuous improvement in the operation of the proposed project. (10 points)

(5) The extent to which the results of the proposed project are to be disseminated in ways that will enable others to use the information or strategies. (5 points)

C. *Quality of the Project Evaluation (up to 25 points).*

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors:

(1) The extent to which the methods of evaluation will, if well implemented, produce evidence about the project's effectiveness that would meet the What Works Clearinghouse standards with or

without reservations as described in the What Works Clearinghouse Handbook (as defined in this notice). (15 points)

(2) The extent to which the evaluation plan clearly articulates the key project components, mediators, and outcomes, as well as a measurable threshold for acceptable implementation. (5 points)

(3) The extent to which the methods of evaluation will provide valid and reliable performance data on relevant outcomes. (5 points)

In evaluating an application for Absolute Priority 3, the Secretary considers the following criteria:

A. *Quality of the Project Design (up to 45 points).*

The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(1) The extent to which professional learning funded through the stipend will replace existing mandatory professional development for participating teachers at the following levels:

(i) Replacing less than 20 percent of required professional learning. (0 points)

(ii) Replacing 20 percent of required professional learning. (5 points)

(iii) Replacing 40 percent of required professional learning. (10 points)

(iv) Replacing 60 percent of required professional learning. (15 points)

(v) Replacing 80 percent of required professional learning. (20 points)

(vi) Replacing 100 percent of required professional learning. (25 points)

(2) The adequacy of plans to ensure that stipends are appropriately used for high-quality professional learning. (5 points)

(3) The extent to which the proposed project will offer teachers flexibility and autonomy regarding the extent of the choice teachers have in selecting their professional learning. (5 points)

(4) The likelihood that the procedures and resources for teachers result in a simple process to select or request professional learning based on their professional learning needs and those identified needs of high-need students. (5 points)

(5) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable. (5 points)

B. *Adequacy of Resources and Quality of the Management Plan (up to 30 points).*

The Secretary considers the adequacy of resources and the quality of the management plan for the proposed project. In determining the adequacy of resources and quality of the management plan for the proposed project, the Secretary considers the following factors:

(1) The sufficiency of the stipend amount to enable professional learning funded through the stipend to replace a significant portion of existing mandatory professional development for participating teachers. (5 points)

(2) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project. (5 points)

(3) The extent to which the proposed payment structure will enable teachers to have an opportunity to apply for and use the stipend with minimal burden. (5 points)

(4) The qualifications, including relevant training and experience, of key project personnel. (5 points)

(5) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks. (5 points)

(6) The adequacy of procedures for leveraging the stipend program to inform continuous improvement and systematic changes to professional learning. (5 points)

C. *Quality of the Project Evaluation (up to 25 points).*

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors:

(1) The extent to which the methods of evaluation will, if well implemented, produce evidence about the project's effectiveness that would meet the What Works Clearinghouse standards with or without reservations as described in the What Works Clearinghouse Handbook (as defined in 34 CFR 77.1(c)). (15 points)

(2) The extent to which the evaluation plan clearly articulates the key project components, mediators, and outcomes, as well as a measurable threshold for acceptable implementation. (5 points)

(3) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes. (5 points)

Note: Applicants may wish to review the following technical assistance resources on evaluation: (1) WWC Procedures and Standards Handbooks: *https://ies.ed.gov/ncee/wwc/Handbooks;* (2) ''Technical Assistance Materials for Conducting Rigorous Impact Evaluations'': *http://ies.ed.gov/ncee/projects/evaluationTA.asp;* and (3) IES/NCEE Technical Methods papers: *http://ies.ed.gov/ncee/tech_methods/.* In addition, applicants may view an optional webinar recording that was hosted by the Institute of Education Sciences. The webinar focused on more rigorous evaluation designs, discussing strategies for designing and executing experimental studies that meet WWC evidence standards without reservations. This webinar is available at: *http://ies.ed.gov/ncee/wwc/Multimedia/18.*

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

Before making awards, we will screen applications submitted in accordance with the requirements in this notice to determine whether applications have met eligibility and other requirements. This screening process may occur at various stages of the process; applicants that are determined to be ineligible will not receive a grant, regardless of peer reviewer scores or comments.

Peer reviewers will read, prepare a written evaluation of, and score the assigned applications, using the selection criteria provided in this notice.

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition

threshold (currently $250,000), under 2 CFR 200.205(a)(2), we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20(c).

Note: The evaluation report is a specific deliverable under an Early-phase grant that grantees must make available to the public. Additionally, EIR grantees are encouraged to submit final studies resulting from research supported in whole or in part by EIR to the Educational Resources Information Center (*http://eric.ed.gov*).

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* The overall purpose of the EIR program is to expand the implementation of, and investment in, innovative practices that are demonstrated to have an impact on improving student achievement and attainment for high-need students. We have established several performance measures (as defined in this notice) for the Early-phase grants.

Annual performance measures: (1) The percentage of grantees that reach their annual target number of students as specified in the application; (2) the percentage of grantees that reach their annual target number of high-need students as specified in the application; (3) the percentage of grantees with ongoing well-designed and independent evaluations designed to provide performance feedback to inform project design; (4) the percentage of grantees with ongoing well-designed and independent evaluations that will provide evidence of their effectiveness at improving student outcomes; (5) the percentage of grantees that implement an evaluation that provides information about the key elements and the approach of the project so as to facilitate testing, development, or replication in other settings; and (6) the cost per student served by the grant.

Cumulative performance measures: (1) The percentage of grantees that reach the targeted number of students specified in the application; (2) the percentage of grantees that reach the targeted number of high-need students specified in the application; (3) the percentage of grantees that use evaluation data to make changes to their practice(s); (4) the percentage of grantees that implement a completed well-designed, well-implemented, and independent evaluation that provides evidence of their effectiveness at improving student outcomes; (5) the percentage of grantees with a completed evaluation that provides information about the key elements and the approach of the project so as to facilitate testing, development, or replication in other settings; and (6) the cost per student served by the grant.

Project-Specific Performance Measures: Applicants must propose project-specific performance measures and performance targets (as defined in this notice) consistent with the objectives of the proposed project. Applications must provide the following information as directed under 34 CFR 75.110(b) and (c):

(1) Performance measures. How each proposed performance measure would accurately measure the performance of the project and how the proposed performance measure would be consistent with the performance measures established for the program funding the competition.

(2) Baseline (as defined in this notice) data. (i) Why each proposed baseline is valid; or (ii) if the applicant has determined that there are no established baseline data for a particular performance measure, an explanation of why there is no established baseline and of how and when, during the project period, the applicant would establish a valid baseline for the performance measure.

(3) Performance targets. Why each proposed performance target is ambitious yet achievable compared to

the baseline for the performance measure and when, during the project period, the applicant would meet the performance target(s).

(4) Data collection and reporting. (i) The data collection and reporting methods the applicant would use and why those methods are likely to yield reliable, valid, and meaningful performance data; and (ii) the applicant's capacity to collect and report reliable, valid, and meaningful performance data, as evidenced by high-quality data collection, analysis, and reporting in other projects or research.

All grantees must submit an annual performance report with information that is responsive to these performance measures.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* Braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Frank T. Brogan,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2020–15994 Filed 7–28–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0123]

Agency Information Collection Activities; Comment Request; Education Stabilization Fund—Governor's Emergency Education Relief Fund (GEER) Recipient Data Collection Form

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before September 28, 2020.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2020–SCC–0123. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance, Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Gabriella Tanner, 202–453–6129, or email *geerf@ed.gov.*

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Education Stabilization Fund—Governor's Emergency Education Relief Fund (GEER) Recipient Data Collection Form.

OMB Control Number: 1810–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local and Tribal Organizations; Private Sector.

Total Estimated Number of Annual Responses: 3,326.

Total Estimated Number of Annual Burden Hours: 10,258.

Abstract: This information collection supports the annual collection of data pertaining to the uses of funds under the Governor's Emergency Education Relief Fund (GEER Fund). The Department awards GEER grants to Governors (states) and analogous grants to Outlying Areas for the purpose of providing local educational agencies (LEAs), institutions of higher education (IHEs), and other education related entities with emergency assistance as a result of the coronavirus pandemic. The Department has awarded these grants—to States (governor's offices) based on a formula stipulated in the legislation. (1)

60% on the basis of the State's relative population of individuals aged 5 through 24. (2) 40% on the basis of the State's relative number of children counted under section 1124(c) of the Elementary and Secondary Education Act of 1965 (ESEA). The grants are awarded to Outlying Areas based on the same formula. The information will be reviewed by Department employees to ensure that GEER funds are used in accordance with Sec. 18002(c) of the CARES Act, and will be shared with the public to promote transparency regarding the allocation and uses of funds.

GEER Reporting Requirements: Data collected through this information collection will inform Department monitoring and oversight, and public reporting and is in addition to reporting already required under the Federal Funding Accountability and Transparency Act of 2006 (FFATA), Public Law 109—282, as amended by the Digital Accountability and Transparency Act (DATA Act), Public Law 113—101.

GEER Reporting Timeframe: The anticipated reporting periods and associated deadlines for this information collection are as follows:

The First Annual Report is due on January 29, 2021 and applies to the reporting period from March 13, 2020 through September 30, 2020. The Second Annual Report is due on January 31, 2022 and applies to the reporting period from October 1, 2020 through September 30, 2021. The Third Annual Report is due on March 1, 2023 and applies to the reporting period from October 1, 2021 through December 31, 2022.

Directed Questions: The Department requests input from data submitters and stakeholders on the following directed questions. Please note that in addition to these questions, public comments are encouraged on all of the changes proposed. While these questions are directed to State data submitters, comments from all stakeholders on these topics are welcome.

(1) What data in this form will be difficult to collect or report and why? Are there changes that could be made to improve the quality of the data or reduce the burden?

(2) The Department is interested in reducing the burden of data collection and making use of existing data when at all possible. For example, are the proposed data on LEAs and IHEs available in State data systems? If data are not available in the State data system, is it feasible for States to collect these data from LEAs and IHEs that received GEER funding?

(3) Will the proposed method for collecting the number of FTE positions created or retained as a result of GEER funds awarded to the State yield accurate data? Is there an alternative methodology that would improve the accuracy of the data?

(4) What changes should be made to the form to accommodate data collection from the Outlying Areas of the United States, specifically: The U.S. Virgin Islands (VI), Guam (GU), the Commonwealth of the Northern Mariana Islands (CNMI), and American Samoa (AS)?

Dated: July 24, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–16444 Filed 7–28–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; State Personnel Development Grants

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications (NIA) for fiscal year (FY) 2020 for the State Personnel Development Grants (SPDG) program, Catalog of Federal Domestic Assistance (CFDA) number 84.323A. This notice relates to the approved information collection under OMB control number 1820–0028.

DATES:

Applications Available: July 29, 2020.

Deadline for Transmittal of Applications: September 10, 2020.

Pre-Application Webinar Information: No later than August 3, 2020, OSERS will post pre-recorded informational webinars designed to provide technical assistance to interested applicants. The webinars may be found at *www2.ed.gov/fund/grant/apply/osep/new-osep-grants.html.*

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.*

FOR FURTHER INFORMATION CONTACT: Jennifer Coffey, U.S. Department of Education, 400 Maryland Avenue SW, Room 5161, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 245–6673. Email: *jennifer.coffey@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of this program is to assist State educational agencies (SEAs) in reforming and improving their systems for personnel preparation and professional development in early intervention, educational, and transition services in order to improve results for children with disabilities.

Priorities: This notice contains three absolute priorities. In accordance with 34 CFR 75.105(b)(2)(iv), Absolute Priority 1 is from the notice of final priorities and definitions published in the **Federal Register** on August 2, 2012 (77 FR 45944) (2012 NFP). Absolute Priority 2 is from sections 651 through 655 of IDEA, as amended by the Every Student Succeeds Act (ESSA). Absolute Priority 3 is from the notice of final priority and definitions for this program published elsewhere in this issue of the **Federal Register** (2020 NFP).

Under this competition, Absolute Priority 3 constitutes its own funding category, and the Department intends to award one-third of the SPDG grants under this competition to grants under Absolute Priority 3 provided applications of sufficient quality are submitted. Applications will be rank ordered separately for Absolute Priority 3. Therefore, applicants must clearly identify if the proposed project addresses Absolute Priority 3.

Absolute Priorities: For FY 2020 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are absolute priorities. Applicants must address Absolute Priorities 1 and 2. They may also choose to address Absolute Priority 3. Under 34 CFR 75.105(c)(3), we consider only applications that meet all of the priorities that they choose to address.

These priorities are:

Absolute Priority 1: Effective and Efficient Delivery of Professional Development.

The Department establishes a priority to assist SEAs in reforming and

improving their systems for personnel (as that term is defined in section 651(b) of IDEA) preparation and professional development of individuals providing early intervention, educational, and transition services in order to improve results for children with disabilities.

In order to meet this priority, an applicant must demonstrate in the SPDG State Plan it submits, as part of its application under section 653(a)(2) of IDEA, that its proposed project will—

(1) Use evidence-based professional development practices that will increase implementation of evidence-based practices and result in improved outcomes for children with disabilities;

(2) Provide ongoing assistance to personnel receiving SPDG-supported professional development that supports the implementation of evidence-based practices with fidelity (as defined in this notice); and

(3) Use technology to more efficiently and effectively provide ongoing professional development to personnel, including to personnel in rural areas and to other populations, such as personnel in urban or high-need local educational agencies (LEAs) (as defined in this notice).

Absolute Priority 2: State Personnel Development Grants.

Statutory Requirements. To meet this priority, an applicant must meet the following statutory requirements:

1. State Personnel Development Plan.

An applicant must submit a State Personnel Development Plan that identifies and addresses the State and local needs for the personnel preparation and professional development of personnel, as well as individuals who provide direct supplementary aids and services to children with disabilities, and that—

(a) Is designed to enable the State to meet the requirements of section 612(a)(14) of IDEA, as amended by the ESSA and section 635(a)(8) and (9) of IDEA;

(b) Is based on an assessment of State and local needs that identifies critical aspects and areas in need of improvement related to the preparation, ongoing training, and professional development of personnel who serve infants, toddlers, preschoolers, and children with disabilities within the State, including—

(1) Current and anticipated personnel vacancies and shortages; and

(2) The number of preservice and inservice programs;

(c) Is integrated and aligned, to the maximum extent possible, with State plans and activities under the Elementary and Secondary Education Act of 1965, as amended (ESEA); the Rehabilitation Act of 1973, as amended; and the Higher Education Act of 1965, as amended (HEA);

(d) Describes a partnership agreement that is in effect for the period of the grant, which agreement must specify—

(1) The nature and extent of the partnership described in accordance with section 652(b) of IDEA and the respective roles of each member of the partnership, including, if applicable, an individual, entity, or agency other than the SEA that has the responsibility under State law for teacher preparation and certification; and

(2) How the SEA will work with other persons and organizations involved in, and concerned with, the education of children with disabilities, including the respective roles of each of the persons and organizations;

(e) Describes how the strategies and activities the SEA uses to address identified professional development and personnel needs will be coordinated with activities supported with other public resources (including funds provided under Part B and Part C of IDEA and retained for use at the State level for personnel and professional development purposes) and private resources;

(f) Describes how the SEA will align its personnel development plan with the plan and application submitted under sections 1111 and 2101(d), respectively, of the ESEA;

(g) Describes strategies the SEA will use to address the identified professional development and personnel needs and how such strategies will be implemented, including—

(1) A description of the programs and activities that will provide personnel with the knowledge and skills to meet the needs of, and improve the performance and achievement of, infants, toddlers, preschoolers, and children with disabilities; and

(2) How such strategies will be integrated, to the maximum extent possible, with other activities supported by grants funded under section 662 of IDEA, as amended by the ESSA;

(h) Provides an assurance that the SEA will provide technical assistance to LEAs to improve the quality of professional development available to meet the needs of personnel who serve children with disabilities;

(i) Provides an assurance that the SEA will provide technical assistance to entities that provide services to infants and toddlers with disabilities to improve the quality of professional development available to meet the needs of personnel serving those children;

(j) Describes how the SEA will recruit and retain teachers who meet the qualifications described in section 612(a)(14)(C) of IDEA, as amended by the ESSA, and other qualified personnel in geographic areas of greatest need;

(k) Describes the steps the SEA will take to ensure that economically disadvantaged and minority children are not taught at higher rates by teachers who do not meet the qualifications described in section 612(a)(14)(C) of IDEA, as amended by the ESSA; and

(l) Describes how the SEA will assess, on a regular basis, the extent to which the strategies implemented have been effective in meeting the performance goals described in section 612(a)(15) of IDEA, as amended by the ESSA.

2. Partnerships.

(a) Required Partners.

Applicants must establish a partnership with LEAs and other State agencies involved in, or concerned with, the education of children with disabilities, including—

(1) Not less than one institution of higher education (IHE); and

(2) The State agencies responsible for administering Part C of IDEA, early education, child care, and vocational rehabilitation programs.

(b) Other Partners.

An SEA must work in partnership with other persons and organizations involved in, and concerned with, the education of children with disabilities, which may include—

(1) The Governor;

(2) Parents of children with disabilities ages birth through 26;

(3) Parents of nondisabled children ages birth through 26;

(4) Individuals with disabilities;

(5) Parent training and information centers or community parent resource centers funded under sections 671 and 672 of IDEA, respectively;

(6) Community-based and other nonprofit organizations involved in the education and employment of individuals with disabilities;

(7) Personnel as defined in section 651(b) of IDEA;

(8) The State advisory panel established under Part B of IDEA;

(9) The State interagency coordinating council established under Part C of IDEA;

(10) Individuals knowledgeable about vocational education;

(11) The State agency for higher education;

(12) Public agencies with jurisdiction in the areas of health, mental health, social services, and juvenile justice;

(13) Other providers of professional development who work with infants, toddlers, preschoolers, and children with disabilities;

(14) Other individuals; and

(15) An individual, entity, or agency as a partner in accordance with section 652(b)(3) of IDEA, if State law assigns responsibility for teacher preparation and certification to an individual, entity, or agency other than the SEA.

3. Use of Funds.

(a) Professional Development Activities—Each SEA that receives a grant under this program must use the grant funds to support activities in accordance with the State's Personnel Development Plan, including one or more of the following:

(1) Carrying out programs that provide support to both special education and regular education teachers of children with disabilities and principals, such as programs that—

(i) Provide teacher mentoring, team teaching, reduced class schedules and caseloads, and intensive professional development;

(ii) Use standards or assessments for guiding beginning teachers that are consistent with challenging State academic achievement standards and with the requirements for professional development, as defined in section 8101 of the ESEA; and

(iii) Encourage collaborative and consultative models of providing early intervention, special education, and related services.

(2) Encouraging and supporting the training of special education and regular education teachers and administrators to effectively use and integrate technology—

(i) Into curricula and instruction, including training to improve the ability to collect, manage, and analyze data to improve teaching, decision making, school improvement efforts, and accountability;

(ii) To enhance learning by children with disabilities; and

(iii) To effectively communicate with parents.

(3) Providing professional development activities

that—

(i) Improve the knowledge of special education and regular education teachers concerning—

(A) The academic and developmental or functional needs of students with disabilities; or

(B) Effective instructional strategies, methods, and skills, and the use of State academic content standards and student academic achievement standards, and State assessments, to improve teaching practices and student academic achievement;

(ii) Improve the knowledge of special education and regular education teachers and principals and, in appropriate cases, paraprofessionals, concerning effective instructional practices, and that—

(A) Provide training in how to teach and address the needs of children with different learning styles and children who are English learners;

(B) Involve collaborative groups of teachers, administrators, and, in appropriate cases, related services personnel;

(C) Provide training in methods of—

(I) Positive behavioral interventions and supports to improve student behavior in the classroom;

(II) Scientifically based reading instruction, including early literacy instruction;

(III) Early and appropriate interventions to identify and help children with disabilities;

(IV) Effective instruction for children with low-incidence disabilities;

(V) Successful transitioning to postsecondary opportunities; and

(VI) Classroom-based techniques to assist children prior to referral for special education;

(D) Provide training to enable personnel to work with and involve parents in their child's education, including parents of low income and children with disabilities who are English learners;

(E) Provide training for special education personnel and regular education personnel in planning, developing, and implementing effective and appropriate individualized education programs (IEPs); and

(F) Provide training to meet the needs of students with significant health, mobility, or behavioral needs prior to serving those students;

(iii) Train administrators, principals, and other relevant school personnel in conducting effective IEP meetings; and

(iv) Train early intervention, preschool, and related services providers, and other relevant school personnel in conducting effective individualized family service plan (IFSP) meetings.

(4) Developing and implementing initiatives to promote the recruitment and retention of special education teachers who meet the qualifications described in section 612(a)(14)(C) of IDEA, as amended by the ESSA, particularly initiatives that have proven effective in recruiting and retaining teachers who meet those qualifications, described in section 612(a)(14)(C) of IDEA, as amended by the ESSA, including programs that provide—

(i) Teacher mentoring from exemplary special education teachers, principals, or superintendents;

(ii) Induction and support for special education teachers during their first three years of employment as teachers; or

(iii) Incentives, including financial incentives, to retain special education teachers who have a record of success in helping students with disabilities.

(5) Carrying out programs and activities that are designed to improve the quality of personnel who serve children with disabilities, such as—

(i) Innovative professional development programs (which may be provided through partnerships with IHEs), including programs that train teachers and principals to integrate technology into curricula and instruction to improve teaching, learning, and technology literacy and that are consistent with the definition of professional development in section 8101 of the ESEA; and

(ii) The development and use of proven, cost effective strategies for the implementation of professional development activities, such as through the use of technology and distance learning.

(6) Carrying out programs and activities that are designed to improve the quality of early intervention personnel, including paraprofessionals and primary referral sources, such as—

(i) Professional development programs to improve the delivery of early intervention services;

(ii) Initiatives to promote the recruitment and retention of early intervention personnel; and

(iii) Interagency activities to ensure that early intervention personnel are adequately prepared and trained.

(b) Other Activities—Each SEA that receives a grant under this program must use the grant funds to support activities in accordance with the State's Personnel Development Plan, including one or more of the following:

(1) Reforming special education and regular education teacher certification (including re-certification) or licensing requirements to ensure that—

(i) Special education and regular education teachers have—

(A) The training and information necessary to address the full range of needs of children with disabilities across disability categories; and

(B) The necessary subject matter knowledge and teaching skills in the academic subjects that the teachers teach;

(ii) Special education and regular education teacher certification (including re-certification) or licensing requirements are aligned with challenging State academic content standards; and

(iii) Special education and regular education teachers have the subject

matter knowledge and teaching skills, including technology literacy, necessary to help students with disabilities meet challenging State academic achievement standards.

(2) Programs that establish, expand, or improve alternative routes for State certification of special education teachers for individuals with a baccalaureate or master's degree who meet the qualifications described in section 612(a)(14)(C)of IDEA, as amended by the ESSA, including mid-career professionals from other occupations, paraprofessionals, and recent college or university graduates with records of academic distinction who demonstrate the potential to become highly effective special education teachers.

(3) Teacher advancement initiatives for special education teachers that promote professional growth and emphasize multiple career paths (such as paths to becoming a career teacher, mentor teacher, or exemplary teacher) and pay differentiation.

(4) Developing and implementing mechanisms to assist LEAs and schools in effectively recruiting and retaining special education teachers who meet the qualifications described in section 612(a)(14)(C) of IDEA, as amended by the ESSA.

(5) Reforming tenure systems, implementing teacher testing for subject matter knowledge, and implementing teacher testing for State certification or licensure, consistent with title II of the HEA (20 U.S.C. 1021 *et seq.*).

(6) Funding projects to promote reciprocity of teacher certification or licensing between or among States for special education teachers, except that no reciprocity agreement developed under this absolute priority may lead to the weakening of any State teacher certification or licensing requirement.

(7) Assisting LEAs to serve children with disabilities through the development and use of proven, innovative strategies to deliver intensive professional development programs that are both cost effective and easily accessible, such as strategies that involve delivery through the use of technology, peer networks, and distance learning.

(8) Developing, or assisting LEAs in developing, merit-based performance systems and strategies that provide differential and bonus pay for special education teachers.

(9) Supporting activities that ensure that teachers are able to use challenging State academic content standards and student academic achievement standards, and State assessments for all children with disabilities, to improve instructional practices and improve the academic achievement of children with disabilities.

(10) When applicable, coordinating with, and expanding centers established under section 2113(c)(18) of the ESEA, as amended by the No Child Left Behind Act of 2002, to benefit special education teachers.

(c) Contracts and Subgrants—An SEA that receives a grant under this program—

(1) Must award contracts or subgrants to LEAs, IHEs, parent training and information centers, or community parent resource centers, as appropriate, to carry out the State Personnel Development Plan; and

(2) May award contracts and subgrants to other public and private entities, including the lead agency under Part C of IDEA, to carry out the State plan.

(d) Use of Funds for Professional Development—An SEA that receives a grant under this program must use—

(1) Not less than 90 percent of the funds the SEA receives under the grant for any fiscal year for the Professional Development Activities described in paragraph (a); and

(2) Not more than 10 percent of the funds the SEA receives under the grant for any fiscal year for the Other Activities described in paragraph (b).

Absolute Priority 3: Choice in Professional Development.

Priority:

The purpose of this priority is to fund SPDG grants to SEAs that empower teachers and other personnel to select professional development activities that meet their individual needs to improve results for children with disabilities. States will meet the priority if they describe in their application how they will develop personalized professional development projects to carry out their State plan under section 653 of IDEA and implement professional development activities that are consistent with the use of funds provisions in section 654 of IDEA. This would be accomplished by using funds under the SPDG program for stipends or other mechanisms to provide personnel with choice in selecting professional development options that will count toward State or local professional development requirements, as appropriate, such as the number of hours personnel must fill or the competencies they must acquire to obtain or retain certification, and that are designed to meet their individual needs and thus improve results for children with disabilities.

Application Requirements: For FY 2020 and any subsequent year in which we make awards from the list of unfunded applications from this competition, the following application requirements apply.

Applicants must—

(a) Demonstrate, in the narrative section of the application under ''Significance,'' how the proposed project will develop personalized professional development activities using stipends or other mechanisms that provide personnel choice in professional development options designed to meet their individual needs and count toward State or local professional development requirements and thus improve results for children with disabilities;

(b) Describe how the State will select the individual(s) or groups of personnel that will be provided with professional development options, including the extent to which applicants will prioritize selecting individuals or groups of personnel serving rural children with disabilities or disadvantaged children with disabilities, such as children from low-income families. If applicable, applicants should specify how they will prioritize personnel if demand for professional development among the individuals or groups of personnel that the applicant proposes to serve exceeds what available funds can support;

(c) Describe how the State will create a list of approved professional development options that meet the requirements of the SPDG program. This description should include how the applicant will engage with a range of stakeholders, including school administrators, personnel serving students with disabilities, families of students with disabilities and individuals with disabilities, and other State or local agencies serving individuals with disabilities, such as juvenile justice agencies, to determine which professional development options it will offer. Specifically, professional development options must—

(1) Use evidence-based (as defined in this notice) professional development methods that will increase implementation of evidence-based practices and result in improved outcomes for children with disabilities;

(2) Include ongoing assistance that supports the implementation of evidence-based practices with fidelity (as defined in this notice); and

(3) Use technology to more efficiently and effectively provide ongoing professional development to personnel, including to personnel in rural areas and in urban or high-need local

educational agencies (LEAs) (as defined in this notice);

(d) If applicable, describe the steps that personnel would need to take to request professional development options not already on a list of approved professional development options, the justification that personnel would need to provide to demonstrate how the selected options would improve results for children with disabilities, and how personnel would be notified if their request was approved or disapproved in writing and within 14 days; and

(e) Describe—

(1) The extent to which the proposed project will use professional development practices supported by evidence to support the attainment of identified competencies;

(2) How improvement in implementation of SPDG-supported practices over time will be demonstrated by participants in SPDG professional development activities;

(3) The extent to which the proposed project will use SPDG professional development funds to provide activities designed to sustain the use of SPDG-supported practices;

(4) How the proposed project will determine whether special education teachers who meet the qualifications described in section 612(a)(14)(C) of IDEA, as amended by the ESSA, that have participated in SPDG-supported special education teacher retention activities remain as special education teachers two years after their initial participation in these activities; and

(5) How the proposed project will assess whether and to what extent the project improves outcomes for children with disabilities.

Additional SPDG Requirements

Projects funded under this program must—

(a) Budget for a three-day project directors' meeting in Washington, DC, during each year of the project;

(b) Budget $4,000 annually for support of the SPDG Program website currently administered by the University of Oregon (*www.signetwork.org*); and

(c) If a project receiving assistance under this program authority maintains a website, include relevant information and documents in a form that meets a government or industry-recognized standard for accessibility.

Definitions:

The following definitions apply to this competition. We provide the source of the definitions in parentheses.

Evidence-based means the proposed project component is supported by one or more of strong evidence, moderate evidence, and promising evidence. (34 CFR 77.1)

Experimental study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbook (version 3.0):

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment. (34 CFR 77.1)

Fidelity means the delivery of instruction in the way in which it was designed to be delivered. (77 FR 45944)

High-need LEA means, in accordance with section 2102(3) of the ESEA, an LEA—

(a) That serves not fewer than 10,000 children from families with incomes below the poverty line (as that term is defined in section 8101(41) of the ESEA), or for which not less than 20 percent of the children served by the LEA are from families with incomes below the poverty line; and

(b) For which there is (1) a high percentage of teachers not teaching in the academic subjects or grade levels that the teachers were trained to teach, or (2) a high percentage of teachers with emergency, provisional, or temporary certification or licensing.

Lead agency means the agency designated by the State's Governor under section 635(a)(10) of IDEA and 34 CFR 303.120 that receives funds under section 643 of IDEA to administer the State's responsibilities under part C of IDEA. (34 CFR 303.22)

Local educational agency (LEA) means a public board of education or other public authority legally constituted within a State for either administrative control or direction of, or to perform a service function for, public elementary schools or secondary schools in a city, county, township, school district, or other political subdivision of a State, or for such combination of school districts or counties as are recognized in a State as an administrative agency for its public elementary schools or secondary schools. (Section 602(19) of IDEA (20 U.S.C. 1401(19)))

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers). (34 CFR 77.1)

Promising evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome, based on a relevant finding from one of the following—

(i) A practice guide prepared by WWC reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single study assessed by the Department, as appropriate, that—

(A) Is an experimental study, a quasi-experimental design study, or a well-designed and well-implemented correlational study with statistical controls for selection bias (*e.g.,* a study using regression methods to account for differences between a treatment group and a comparison group); and

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome. (34 CFR 77.1)

Quasi-experimental design study means a study using a design that attempts to approximate an experimental study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.,* establishment of baseline equivalence of the groups being compared), can meet WWC

standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbook. (34 CFR 77.1)

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program. (34 CFR 77.1)

State educational agency means the State board of education or other agency or officer primarily responsible for the State supervision of public elementary schools and secondary schools, or, if there is no such officer or agency, an officer or agency designated by the Governor or by State law. (Section 602(32) of IDEA (20 U.S.C. 1401(32)))

Strong evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations and settings proposed to receive that component, based on a relevant finding from one of the following—

(i) A practice guide prepared by the WWC using version 2.1 or 3.0 of the WWC Handbook reporting a ''strong evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1 or 3.0 of the WWC Handbook reporting a ''positive effect'' on a relevant outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study reviewed and reported by the WWC using version 2.1 or 3.0 of the WWC Handbook, or otherwise assessed by the Department using version 3.0 of the WWC Handbook, as appropriate, and that—

(A) Meets WWC standards without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1 or 3.0 of the WWC Handbook; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy this requirement. (34 CFR 77.1)

What Works Clearinghouse Handbook (WWC Handbook) means the standards and procedures set forth in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (incorporated by reference, see 34 CFR 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the Handbook documentation. (34 CFR 77.1)

Note: The What Works Clearinghouse Procedures and Standards Handbook (Version 3.0), as well as the more recent What Works Clearinghouse Handbooks released in October 2017 (Version 4.0) and January 2020 (Version 4.1), are available at *https://ies.ed.gov/ncee/wwc/Handbooks.*

Program Authority: 20 U.S.C. 1451–1455.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The 2012 NFP. (e) The 2020 NFP.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

Note: Projects must be awarded and operated in a manner consistent with the nondiscrimination requirements contained in the U.S. Constitution and the Federal civil rights laws.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $11,727,418.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2021 from the list of unfunded applications from this competition.

Estimated Range of Awards: $500,000–$2,100,000 (for the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico). In the case of outlying areas (United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands), awards will be not less than $80,000.

Note: We will set the amount of each award after considering—

(1) The amount of funds available for making the grants;

(2) The relative population of the State or outlying area;

(3) The types of activities proposed by the State or outlying area;

(4) The alignment of proposed activities with section 612(a)(14) of IDEA, as amended by the ESSA;

(5) The alignment of proposed activities with State plans and applications submitted under sections 1111 and 2101(d), respectively, of the ESEA; and

(6) The use, as appropriate, of research and instruction supported by evidence.

Estimated Average Size of Awards: $900,000 excluding the outlying areas.

Estimated Number of Awards: 11.

Note: The Department is not bound by any estimates in this notice.

Project Period: Not less than one year and not more than five years.

III. Eligibility Information

1. *Eligible Applicants:* An SEA of one of the 50 States, the District of Columbia, or the Commonwealth of Puerto Rico or an outlying area (United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands).

Note: Public Law 95–134, which permits the consolidation of grants to the outlying areas, does not apply to funds received under this competition.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application. Under 34 CFR 75.708(e), a grantee may contract for supplies, equipment, and other services in accordance with 2 CFR part 200.

4. *Other General Requirements:*

(a) Recipients of funding under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Applicants for, and recipients of, funding must, with respect to the aspects of their proposed project relating to Absolute Priorities 2 and 3, involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to

follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf,* which contain requirements and information on how to submit an application.

2. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review in order to make awards by the end of FY 2020.

3. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit:* The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 70 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.
- Use a font that is 12 point or larger.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the recommended page limit does apply to all of the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are as follows:

(a) *Significance (20 points).*

(1) The Secretary considers the significance of the proposed project.

(2) In determining the significance of the proposed project, the Secretary considers the following factors:

(i) The extent to which the proposed project is part of a comprehensive effort to improve teaching and learning and support rigorous academic standards for students.

(ii) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses.

(iii) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services.

(iv) The likelihood that the proposed project will result in system change or improvement.

(b) *Quality of the project design (25 points).*

(1) The Secretary considers the quality of the design of the proposed project.

(2) In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(i) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(ii) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs.

(iii) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services.

(iv) The extent to which the design of the proposed project reflects up-to-date knowledge from research and effective practice.

(v) The extent to which the proposed project will establish linkages with other appropriate agencies and organizations providing services to the target population.

(c) *Quality of the project personnel (10 points).*

(1) The Secretary considers the quality of the personnel who will carry out the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of the project director or principal investigator.

(ii) The qualifications, including relevant training and experience, of key project personnel.

(d) *Adequacy of resources and management plan (20 points).*

(1) The Secretary considers the adequacy of resources and management plan for the proposed project.

(2) In determining the adequacy of resources for the proposed project, the Secretary considers the following factors:

(i) The relevance and demonstrated commitment of each partner in the proposed project to the implementation and success of the project.

(ii) The extent to which the budget is adequate to support the proposed project.

(iii) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(iv) How the applicant will ensure that a diversity of perspectives are brought to bear in the operation of the proposed project, including those of parents, teachers, the business community, a variety of disciplinary and professional fields, recipients or beneficiaries of services, or others, as appropriate.

(v) The potential for continued support of the project after Federal funding ends, including, as appropriate, the demonstrated commitment of appropriate entities to such support.

(e) *Quality of the project evaluation (25 points).*

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(ii) The extent to which the methods of evaluation are appropriate to the context within which the project operates.

(iii) The extent to which the methods of evaluation provide for examining the effectiveness of project implementation strategies.

(iv) The extent to which the methods of evaluation include the use of

objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

(v) The extent to which the evaluation will provide guidance about effective strategies suitable for replication or testing in other settings.

(vi) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(vii) The extent to which the evaluation plan clearly articulates the key project components, mediators, and outcomes, as well as a measurable threshold for acceptable implementation.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

5. *Performance Measures:* Under the Government Performance Results Modernization Act of 2010, the Department has established a set of performance measures, including long-term measures, that are designed to

yield information on various aspects of the effectiveness and quality of the SPDG Program. These measures assess the extent to which—

- Projects use professional development practices supported by evidence to support the attainment of identified competencies;
- Participants in SPDG professional development demonstrate improvement in implementation of SPDG-supported practices over time;
- Projects use SPDG professional development funds to provide activities designed to sustain the use of SPDG-supported practices;
- Special education teachers who meet the qualifications described in section 612(a)(14)(C) of IDEA, as amended by the ESSA, and who have participated in SPDG-supported special education teacher retention activities remain as special education teachers two years after their initial participation in these activities; and
- Projects improve outcomes for children with disabilities.

Each grantee funded under this competition must collect and annually report data related to its performance on these measures in the project's annual and final performance report to the Department in accordance with section 653(d) of IDEA and 34 CFR 75.590. Applicants should discuss in the application narrative how they propose to collect performance data for these measures.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Mark Schultz,

Commissioner, Rehabilitation Services Administration. Delegated the authority to perform the functions and duties of the Assistant Secretary for the Office of Special Education and Rehabilitative Services.

[FR Doc. 2020–16549 Filed 7–27–20; 4:15 pm]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket ID ED–2020–OESE–0025]

Final Priorities, Requirements, Definition, and Selection Criteria—Education Innovation and Research—Teacher-Directed Professional Learning Experiences

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

ACTION: Final priorities, requirements, definition, and selection criteria.

SUMMARY: The Assistant Secretary for Elementary and Secondary Education announces priorities, requirements, definition, and selection criteria under the Education Innovation and Research (EIR) program, Catalog of Federal Domestic Assistance (CFDA) numbers 84.411A/B/C. The Assistant Secretary may use these priorities, requirements, definition, and selection criteria for a competition in fiscal year (FY) 2020 and in later years. The Department intends these priorities, requirements, definition, and selection criteria to support competitions under the EIR program for the purpose of developing, implementing, and evaluating teacher-directed professional learning projects designed to enhance instructional practice and improve achievement and attainment for high-need students.

DATES: These priorities, requirements, definition, and selection criteria are effective August 28, 2020.

FOR FURTHER INFORMATION CONTACT: Ashley Brizzo. U.S. Department of Education, 400 Maryland Avenue SW, Room 3E325, Washington, DC 20202. Telephone: (202) 453–7122. Email: *EIR@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Purpose of Program: The EIR program, established under section 4611 of the Elementary and Secondary Education Act, as amended (ESEA), provides funding to create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based, field-initiated innovations to improve student achievement and attainment for high-need students; and rigorously evaluate such innovations. The EIR program is designed to generate and validate solutions to persistent education challenges and to support the expansion of those solutions to serve substantially larger numbers of students.

Program Authority: Section 4611 of the ESEA, 20 U.S.C. 7261.

We published a notice of proposed priorities, requirements, definition, and selection criteria for this program in the **Federal Register** on April 13, 2020 (85 FR 20455) (the NPP). That document contained background information and our reasons for proposing the priorities, requirements, definition, and selection criteria for Education Innovation and Research—Teacher-Directed Professional Learning Experiences.

Public Comment: In response to our invitation in the NPP, 89 parties submitted comments pertinent to the proposed priorities, requirements, definition, and selection criteria. We group major issues according to subject. Generally, we do not address comments that are outside the scope of the proposed priorities, requirements, definition, and selection criteria.

Analysis of Comments and Changes: An analysis of the comments and of any changes in the priorities, requirements, definition, and selection criteria since publication of the NPP follows.

General Comments; Priority 1—Teacher-Directed Professional Learning

Comments: Among the 19 comments of general support, commenters indicated overall support for the

concept of teachers choosing their own professional learning, emphasized the need for flexibility, and acknowledged the insufficiency of the current status of teacher professional development. Five commenters expressed that one-size-fits-all professional development does not work and that the ability for teachers to differentiate and customize their learning is important. Two commenters specifically noted having participated in similar stipend programs in the past that those commenters found to be successful. In addition to the 19 comments of support, 33 commenters also expressed support for the general idea but offered specific feedback, and their comments are accounted for in the sections that follow.

Discussion: We appreciate the support for these proposed priorities, requirements, definition, and selection criteria and agree that teachers' differentiation and customization of their learning is important.

Changes: None.

Comments: Thirty-seven commenters opposed the general idea of teacher-driven professional learning stipends, including Proposed Priority 1. Commenters opposed the use of EIR funds for this purpose based on the need for prior evidence of the success of stipend programs (15 comments) and expressed concern about narrowing the focus of EIR or undermining other investments such as ESEA title II, part A (14 comments). Commenters also offered input about a preference to support collaborative learning (such as a training for all mathematics teachers at a school to uniformly adopt a new approach) instead of individually driven learning (such as one mathematics teacher learning about an innovative approach and applying different methods from the other mathematics teachers) (17 comments). Other commenters expressed concern that not all teachers would have the opportunity to get a stipend, which could exacerbate between-classroom inequities (8 comments). Six commenters expressed their opinion that teacher choice already exists; in their school or district teachers already have a great deal of discretion regarding the professional learning in which they engage. Another six commenters suggested that it is the role of principals, rather than the teachers, themselves, to make decisions about professional development for their teachers given the principal's awareness of school-level needs. Five commenters stated concerns that the concept of teacher-driven professional learning assumes that teachers know what kinds of professional development they need but that they need guidance and support from school and district leaders to identify areas for growth. Related to these comments of general opposition were comments about the need for districts and school leaders to set professional learning priorities aligned to district and school priorities and that the quality of professional learning funded by the stipends might vary; those comments are specifically addressed in the relevant sections that follow.

Discussion: We appreciate these commenters' perspectives. The Department does not agree with the argument that the lack of robust evidence on teacher-driven professional learning is a reason not to hold a competition in this area. For any EIR competition that uses the proposed priorities, the Department intends to build evidence about teacher-selected professional learning consistent with the EIR program's purpose of supporting innovation in education. Additionally, the Department believes that there is sufficient evidence about teacher-directed professional learning that would meet the ''demonstrates a rationale'' evidence requirement should this priority be used in an Early-phase competition; furthermore, applicants must submit sufficient evidence to that end to be eligible for that grant. Moreover, we do think that applicants will apply to meet this lower evidence tier and that the evidence requirement will not be a barrier for applicants.

Regarding comments about narrowing the focus of EIR, the Department annually examines the needs of the field and the existing projects in the EIR portfolio to determine the priorities in that year's competitions. Although commenters raised concerns that such a priority could undermine title II, part A, the Department notes that title II, part A was funded by Congress in FY 2020 and is a separate funding stream with separate statutory requirements. These final priorities provide the Department an opportunity to complement those investments and contribute ideas for ways that teacher voice can be better included in how professional learning is delivered. The Department also includes an assurance that grantees will maintain current fiscal and administrative levels of effort in teacher professional development to help ensure that this program offers an added value to professional learning.

The Department agrees that there is value in collaborative learning, and these priorities allow for teacher-driven decisions to use stipends in such ways including coaching, job shadows, and other peer learning opportunities. Applicants also have the discretion to continue implementing effective collaborative professional learning that already exists.

Although concerns were raised about not all teachers having access to the stipend, the Department believes the applicant is best situated to propose the pool of teachers their proposed program focuses on (*i.e.,* which teachers may request a stipend). If an applicant were concerned about between-classroom inequities, they could recruit teachers who would most likely benefit from personalized support. EIR's focus on innovation is designed to iteratively test feasibility of projects before they are scaled to larger settings and populations. Should the program demonstrate success, such practices could be scaled for broader use. The Department believes this structure is a strategic and responsible means of piloting innovation at a small scale at the nascent phase.

The Department understands that there are a few existing cases of some degree of teacher choice in professional learning. However, it is not a broadly adopted policy or practice in education and is in need of further evaluation. The use of these priorities in EIR is intended to support field-initiated innovations that either build on existing efforts for, or initiate systemic changes that increase, teacher agency. Entities that believe they already have robust systems of teacher-selected professional learning are not required to apply for a grant.

Principals continue to have an important role in supporting teachers and this program is intended to provide an additional set of resources that reinforce principals' efforts to recruit and retain a talented pool of professionals. Given that teachers also can have a vital role in professional learning decisions, this program focuses on enhancing the ways in which teachers are involved in identifying professional learning opportunities.

In response to comments about the ability of teachers to be reflective and self-aware enough to know their needs, the Department highly respects the teaching profession and teachers as professionals. As such, we believe that the teachers who request a stipend are likely to be individuals who are reflective practitioners eager to continue to hone their craft in a way that best supports the students they teach. The Department has structured this priority in a way that would encourage teachers to use data such as student achievement trends, evaluation or observation results, and other feedback about their performance to determine what types of

professional learning the stipend could support.

Changes: None.

Comments: Commenters noted a few areas that were not addressed in the NPP. Nine commenters emphasized a need for an evaluation requirement. Four commenters suggested that the Department encourage piloting or iteration of projects. Four other commenters noted the need for teacher input on project designs. Three commenters expressed concerns about equitable access to the program and the need for an outreach plan to ensure that teachers are aware of the opportunity.

Discussion: The EIR statute includes a requirement for an independent evaluation; as such, it was not necessary to include an evaluation requirement in the proposed priorities, but it is included in EIR notices inviting applications (NIAs). Regarding iterative development of project ideas, EIR already allows for a planning period and specifically encourages continuous improvements in project design and implementation before conducting full-scale implementation and an evaluation of effectiveness. Additionally, the Department may, in EIR competitions that use these final priorities, include selection criteria from the Education Department General Administrative Regulations related to continuous improvement and periodic assessment of progress. The Department appreciates the suggestion for honoring teacher voice and agency by recommending ways that teachers could have input on proposed projects conducted under these priorities; such input is likely to help make systems more relevant and user friendly for teachers. Regarding outreach plans, the Department already included in the NPP a requirement that applicants describe their planned outreach (application requirement (b)) and has maintained that requirement.

Changes: The Department has added new requirements (b)(3) and (b)(4) that provide that applicants must include a summary of the ways in which teachers were involved in the grant application and the ways teachers will be involved in key decisions about the proposed project.

Priority 2—State Educational Agency Partnership

Comments: Fourteen commenters supported a priority for State Educational Agency (SEA) partnerships, including comments such as the necessity of involving SEAs in projects that include teacher-directed professional learning in order to coordinate such learning with certification requirements. Two commenters stated that the SEA role was not necessary for project success due to local control in their State; in these settings there are not statewide professional development requirements, and there is State-mandated district control over professional development.

Discussion: The Department appreciates the comments regarding SEA partnerships and will use these comments to consider including this as a competitive preference priority for any year in which this program is in effect. Regardless of how this priority is used to incentivize SEA partnerships in future competitions, an applicant retains the discretion of deciding whether or not to enter into a partnership with an SEA consistent with the program's eligibility requirements.

Changes: None.

Priority 3—Local Educational Agency Partnership

Comments: Eighteen commenters stated that the local educational agency (LEA) role is critical to teacher-directed professional learning projects. Commenters noted that teachers are employees of the LEA. Other commenters explained that an advantage of such a priority would be that district leaders would ''be able to design the project based on district goals and priorities. Similarly, there were comments about how, through this priority, the LEA would have an opportunity to effect systemic change in that district leaders could create the flexibilities and conditions to support such a project. One commenter stated that an LEA partnership is not necessary if the SEA is engaged.

Discussion: The Department appreciates the comments regarding LEA partnerships and will use these comments to consider including this as a competitive preference priority for any year in which this program is in effect. Regardless of how this priority is used to incentivize LEA partnerships in future competitions, an applicant retains the discretion of deciding whether or not to enter into a partnership with an LEA consistent with the program's eligibility requirements.

Changes: None.

Requirement (a)—Pool of Eligible Teachers

Comments: Two commenters suggested expanded eligibility beyond teachers to included specialized instructional support personnel and school leaders. Another commenter suggested that stipends be paid directly from the Department to teachers.

Discussion: The Department understands that specialized instructional support personnel and school leaders play important roles in schools. However, the Department is interested in exploring this potentially promising idea of teacher-directed professional learning and, pending the successes of such program, will explore opportunities to expand the program to a broader set of school-based professionals.

The Department is required to award grants to eligible entities in a manner consistent with its authorizing statute and thus cannot award funds, such as stipends, directly to teachers.

Changes: None.

Requirement (c)(3)—Mechanisms To Protect Against Fraud, Waste, and Abuse

Comments: Three commenters expressed general concerns about the waste or misuse of stipends, but those comments did not specifically mention application requirement (c)(3).

Discussion: Under application requirement (c)(3), applicants must describe mechanisms to protect against fraud, waste, and abuse (*e.g.,* monitoring systems, reviews for conflicts of interest). The Department believes this requirement, in addition to general requirements for grantees to have fiscal management controls, is sufficient to ensure grantees monitor the usage of funds and guard against misuse.

Changes: None.

Requirement (d)(1)—Replacing No Less Than a Majority

Comments: Proposed application requirement (d)(1) specified how an applicant will be expected to update its policies to offer stipends to teachers such that no less than a majority of existing mandatory professional development would be replaced by teacher-directed professional learning. Three commenters supported allowing teachers to replace a majority of mandatory professional development with teacher-directed professional development, stating that it will allow teachers to fulfill certification requirements while recognizing that there is limited available time for additional professional development. One commenter stated that, because their State requirements are limited, it would not be an issue to replace at least a majority of required professional development with teacher-directed professional development.

Thirty-six commenters opposed the requirement to replace no less than a majority of required professional development. One primary reason for

this concern was the need for States and local leaders to systematically prioritize professional learning based on educational plans and organizational needs such as data trends that reflect a need for more training in a particular area. For example, a few commenters described that there are many required ''non-content'' trainings (*e.g.,* child abuse, bloodborne pathogens) that leave little room for content-based learning. Others noted that the employer (*i.e.,* district) needs to manage their workforce by identifying areas of skills development. Relatedly, a few commenters shared that teacher input should be at the forefront of professional learning decisions, but it should not be the only voice, as district context is also important. Without a mechanism to sufficiently address district-wide or school-wide needs, professional learning could be disjointed (some teachers having training on a district-wide program and others not), incoherent (teacher-selected learning conflicting with locally determined approach), or incomplete (important topics being ignored) according to some of the commenters who opposed the majority replacement requirement. Two commenters specifically stated that meeting this requirement would require a legislative change (namely, the in-service training and licensing requirements set forth by the State legislature) that would be outside of the authority of an applicant. Additional concerns included that the requirement would undermine existing successful collaborative professional learning programs already in place; in particular, that the districts would be forced to release teachers from a team-based coaching program. Commenters proposed alternative approaches, including allowing a smaller portion of professional development to be teacher-directed (*e.g.,* one teacher-selected session per year and the remaining district-selected) or revising the requirement to limit grantees to replacing no *more* than a majority of the existing mandatory professional development, stating that personalized professional learning is only one aspect of high-quality professional learning.

Discussion: The Department appreciates various comments about the potential challenges in replacing a majority of required professional development. The Department believes there continues to be a need for a systemic change in how teachers engage in professional learning. This change includes discontinuing requirements that result in ineffective or irrelevant professional development and do not serve the learning needs of teachers. The Department appreciates that requiring that teachers be allowed to replace at least a majority of the existing mandatory professional development with teacher-directed professional development may not always be feasible and, in response to the comments raised, is making revisions. We believe that a 20 percent threshold (in place of ''majority'') supports incremental, but significant change, and this percentage balances the need to move the needle while still keeping it at a level that a majority of eligible applicants will be able to implement.

Many of the Department's established priorities entail activities that many eligible applicants lack the authority or capacity to do. We recognize that professional development is uniquely tied to rules set by States that most of our eligible applicants will not, if those rules are a barrier, be able to alter. However, the Department has established this priority with the express purpose of altering the way in which teachers engage in professional learning. Each eligible applicant must assess, based on their own unique needs and capabilities, whether to respond to this particular funding opportunity. We note that the EIR NIAs have to date always offered more than two absolute priorities, so applicants that do not feel they are in a position to respond to this priority could consider applying under other priorities.

Changes: The Department has revised language in Proposed Priority 1 and Application Requirement (d)(1) to replace the requirement that teachers be allowed to replace at least a majority of the existing mandatory professional development with teacher-directed professional development with a requirement that teachers be allowed to replace a ''significant portion (no less than 20 percent).'' The Department also revised the language in Selection Criterion (a), including the addition of Selection Criterion (i) to tease out the separate components within the initial criterion.

Requirement (g)(2)—Scaling Practices

Comments: One commenter suggested replacing ''effective'' with ''evidence-based'' in the requirement for applicants to describe mechanisms for incorporating effective practices discovered through teacher-directed professional learning into the professional development curriculum for all teachers.

Discussion: The Department agrees that it is important to scale ''evidence-based'' practices. However, we also intend for this program to allow for innovative professional learning to be tested and, if early indicators show it holds potential promise, then scaling such practices. Applying the rigorous definitions associated with the various evidence tiers could have an unintended consequence of stifling that iterative process.

Changes: None.

Requirement (h)—Assurances

Comments: Regarding the required assurance that an SEA or LEA involved in the project will maintain current fiscal and administrative investments in teacher professional development, one commenter stated that only the State legislature has budget authority, and, as such, the applicant does not have control over whether it can make the assurance. Related to the assurance that stipends will not be limited to a restrictive set of professional learning choices, one commenter noted that applicants need to maintain an ability to restrict use of the stipend so that funds are used for professional development that is instructionally relevant, high quality, and aligned to the identified needs of high-need students. Two commenters stated that grantees should not limit or restrict choices.

Discussion: The Department continues to believe it is critical that this investment does not result in reductions in teacher professional development spending; if a potential applicant is unable to meet the conditions included in this assurance, they are not required to apply. Like many other programs the Department administers, the grant funds are intended to supplement, and not replace the State's professional development investment. While the Department seeks to ensure that grantees do not impose overly restrictive limits on professional learning, the Department agrees that applicants are also required to ensure stipends are used for professional learning that is instructionally relevant, high quality, and aligned to the identified needs of high-need students. As a result, the Department is adding language to application requirement (h)(3) to make clear that the learning options offered may not be ''overly'' restrictive.

Changes: The Department has revised application requirement (h)(3) to clarify that the allowed learning options may not be ''overly'' restrictive.

Definition—Professional Learning

Comments: Nineteen commenters noted that the definition of the term ''professional learning'' did not include elements that they saw as helpful (*e.g.,* collaborative, sustained, and data

driven) and had been included in other legislation. Thus, they suggested using the definition of ''professional development'' in section 8101(42) of the ESEA. Eleven commenters emphasized the importance for teachers to engage in professional learning that is collaborative. A few commenters also stated that it is important that professional learning decisions be informed by data. Commenters also expressed an interest in continuing progress in moving away from ''one-off'' trainings and instead supporting sustained and intensive professional learning.

Discussion: The Department agrees that we should revise the definition of ''professional learning'' to reinforce core elements of high-quality professional learning. However, the Department does not adopt the suggestion to use the ESEA definition of ''professional development'' because this definition includes language about professional development that is not aligned to the focus on teacher agency and voice in professional learning decisions; for example, the ESEA definition references activities that support recruitment efforts and connections to district improvement plans. Instead, the Department has added language to the final definition of ''professional learning'' to require that the learning be ''collaborative,'' ''data-driven,'' and ''part of a sustained and intensive program'' to address points raised in the comments.

Changes: We have revised the definition of ''professional learning'' to require that the learning be ''collaborative,'' ''data-driven,'' and ''part of a sustained and intensive program.''

Selection Criterion (b)—Ensuring Professional Learning Is Instructionally Relevant, High Quality, and Aligned to the Needs of High-Need Students

Comments: We received 11 comments related to the quality of the teacher-directed professional learning funded by the stipends. Commenters emphasized that grantees would need to review requests to ensure the teacher-selected use of the stipend was for high-quality professional learning, given an already saturated market of professional development vendors that range in quality. Those commenters were also concerned that teachers might select professional learning not related to teaching. Another commenter suggested that requested professional learning should not focus on high-need students.

Discussion: The Department agrees that supporting high-quality professional learning is important and, as such, intends to maintain application requirements (f)(2) and (h)(2). Under requirement (f)(2), applicants must describe how teachers' requests meet the ''professional learning'' definition, which includes requirements of being instructionally relevant. Under requirement (h)(2), applicants must assure that project funds will be used for instructionally relevant learning and not activities such as personal enrichment. We also include selection criterion (b) regarding how applicants plan to ensure that professional learning is instructionally relevant, high quality, and aligned to the identified needs of high-need students. The Department will also maintain a focus on high-need students consistent with EIR's authorizing statute,[1] which includes a focus on high-need students.

Changes: The Department did not make substantive changes to this definition but did make a technical edit to remove duplicative language in the criterion that is already addressed in the ''professional learning'' definition.

Selection Criterion (d)—Ease of Process for Teachers

Comments: Three commenters expressed concern about the potential burden on teachers to seek professional learning given the expansive set of options available, potentially making the onus on teachers high and the task of identifying opportunities time consuming.

Discussion: The Department agrees about the importance of minimizing the burden on teachers as reflected in selection criterion (d). Additionally, only eligible teachers who volunteer will participate in the stipend program. Furthermore, application requirements (d)(3) and (f)(1) outline expectations for applicants to have a menu or list of professional learning options. We have included these requirements as a way to support teacher awareness of available opportunities.

Changes: None.

FINAL PRIORITIES:

This notice contains three final priorities.

Priority 1—Teacher-Directed Professional Learning.

Under this priority, an applicant must propose a project in which classroom teachers receive stipends to select professional learning alternatives that are instructionally relevant and meet their individual needs related to instructional practices for high-need students. Additionally, teachers receiving stipends must be allowed the flexibility to replace a significant portion (no less than 20 percent) of existing mandatory professional development with such teacher-directed learning, which must also be allowed to fully count toward any mandatory teacher professional development goals (*e.g.,* professional development hours required as part of certification renewal, designated professional days mandated by districts).

Priority 2—State Educational Agency Partnership.

Under this priority, an applicant must demonstrate it has established a partnership between an eligible entity and an SEA (with either member of the partnership serving as the applicant) to support the proposed project.

Priority 3—Local Educational Agency Partnership.

Under this priority, an applicant must demonstrate it has established a partnership between an eligible entity and an LEA (with either member of the partnership serving as the applicant) to support the proposed project.

Types of Priorities:

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

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

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

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

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

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

[1] ESEA § 4611(a)(1)(A).

Final Requirements

This notice contains eight requirements. We may apply one or more of these requirements in any year in which this program is in effect.

An applicant must—

(a) Describe the pool of teachers eligible to request a stipend, including whether the applicant intends to prioritize eligibility based on content areas, strategic staffing initiatives, or other factors (and including a rationale for how such a determination addresses the needs of high-need students, as defined by the applicant);

(b) Describe the anticipated level of teacher participation, including—

(1) Current information on teacher satisfaction with existing professional learning;

(2) Details on the planned outreach strategy to communicate the stipend opportunity to eligible teachers;

(3) A summary of the ways in which teachers were involved in developing the proposed project; and

(4) A plan for how to include teachers in key decisions about the stipend system;

(c) Describe the proposed stipend structure, including—

(1) Estimated dollar amount per stipend, including associated expenses related to the professional learning (*e.g.,* materials, transportation, etc.);

(2) A rationale for how the estimated dollar amount per stipend is sufficient to ensure access to professional learning activities that are, at minimum, comparable in quality, frequency, and duration to the professional development other non-participating teachers will receive in a given year;

(3) Mechanisms to protect against fraud, waste, and abuse (*e.g.,* monitoring systems, reviews for conflicts of interest); and

(4) Plans for how the applicant will select participants if there is more interest than available stipends (*e.g.,* prioritizing by student need or teacher need, content area, human capital priorities, rubric-based review of requests, lottery);

(d) Describe details about the stipend system, including—

(1) How the applicant will update its policies to offer stipends to teachers such that a significant portion (no less than 20 percent) of existing mandatory professional development is replaced by teacher-directed professional learning, including—

(i) The professional development days or activities from which participating teachers will be released in order to enable teacher-directed learning opportunities and to ensure that teacher-directed learning replaces a significant portion of existing mandatory professional development; or

(ii) Other methods in which participating teachers will be given the flexibility to participate in teacher-directed learning (*e.g.,* by providing release from and substitute teacher coverage during regular instructional days) and how such methods will also ensure participating teachers are released from a significant portion of existing professional development requirements;

(2) How the applicant will ensure that teacher-directed learning will fully substitute for mandatory professional development in meeting mandatory professional development goals or activities (*e.g.,* professional development hours required as part of certification renewal, district- or contract-required professional development hours);

(3) How the applicant will provide information to teachers about professional learning options not previously available to teachers (*e.g.,* list of innovative options, qualified providers, other resources); and

(4) In addition to any list of professional learning options or providers identified by the applicant, mechanisms for teachers to independently select different high-quality, instructionally relevant professional learning activities connected to the achievement and attainment of high-need students (based on teacher-identified needs such as self-assessment surveys, student assessment data, and professional growth plans);

(e) Describe strategies for supporting teachers' implementation of changes in instructional practice as a result of their professional learning;

(f) Describe the process for managing the stipend system, including—

(1) For professional learning options that are among a list of options identified by the applicant: The processes for teachers to submit their requests to participate in those options in place of a previously required training and the processes for direct vendor payment using the stipend; and

(2) For professional learning options selected by a teacher that are not on the applicant's list of options: How the applicant will determine that the activity meets the definition of ''professional learning'' and is reasonable, and what processes the applicant will implement to ensure payment or timely reimbursement to teachers;

(g) Describe the proposed strategy to expand the use of professional learning stipends (pending the results of the evaluation), including—

(1) Plans for continuously improving the stipend system in order to, over time, offer more teachers the opportunity to engage in teacher-directed professional learning and, for participating teachers, ensure a higher percentage of all mandatory professional learning is teacher-directed; and

(2) Mechanisms for incorporating effective practices discovered through teacher-directed professional learning into the professional development curriculum for all teachers; and

(h) Provide an assurance that—

(1) At a minimum, the SEA or LEA involved in the project (as an applicant, partner, or implementation site) will maintain its current fiscal and administrative levels of effort in teacher professional development and allow the professional learning activities funded through the stipends to supplement the level of effort that is typically supported by the applicant;

(2) Project funds will only be used for instructionally relevant professional learning activities and not solely for obtaining advanced degrees, taking or preparing for licensure exams, or for pursuing personal enrichment activities; and

(3) Projects will allow for a variety professional learning options for teachers and not limit use of the stipend to an overly restrictive set of choices (for example, professional learning provided only by the applicant or partners, specific pedagogical or philosophical viewpoints, or organizations with specific methodological stances). The applicant and any application partners will not be the primary financial beneficiaries of the professional learning stipends, and there is no conflict between the applicant, any application partner, and the purpose of providing teachers the autonomy to select their own professional learning opportunities.

FINAL DEFINITION:

This notice includes one final definition. We may apply this definition in any year in which this program is in effect.

Professional learning means instructionally relevant activities to improve and increase classroom teachers'—

(1) Content knowledge;

(2) Understanding of instructional strategies and intervention techniques for high-need students, including how best to analyze and use data to inform such strategies and techniques; and

(3) Classroom management skills to better support high-need students.

Professional learning must be job-embedded or classroom-focused, collaborative, data-driven, part of a sustained and intensive program, and related to the achievement and attainment of high-need students. Professional learning may include innovative activities such as peer shadowing opportunities, virtual mentoring, online modules, professional learning communities, communities of practice, action research, micro-credentials, and coaching support.

FINAL SELECTION CRITERIA:

This notice contains eight selection criteria for evaluating an application under this program. We may apply one or more of these selection criteria in any year in which this program is in effect.

(a) The sufficiency of the stipend amount to enable professional learning funded through the stipend to replace a significant portion of existing mandatory professional development for participating teachers.

(b) The adequacy of plans to ensure that stipends are appropriately used for high-quality professional learning.

(c) The extent to which the proposed project will offer teachers flexibility and autonomy regarding the extent of the choice teachers have in selecting their professional learning.

(d) The likelihood that the procedures and resources for teachers result in a simple process to select or request professional learning based on their professional learning needs and those identified needs of high-need students.

(e) The likelihood that the professional learning supported through the stipends will result in sustained positive changes in teachers' instructional practices.

(f) The likelihood that the professional learning supported through the stipends will result in improved student outcomes.

(g) The extent to which the proposed payment structure will enable teachers to have an opportunity to apply for and use the stipend with minimal burden.

(h) The adequacy of procedures for leveraging the stipend program to inform continuous improvement and systematic changes to professional learning.

(i) The extent to which professional learning funded through the stipend will replace existing mandatory professional development for participating teachers.

Executive Orders 12866, 13563, and 13771

Regulatory Impact Analysis

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

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

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

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

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

This final regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a ''major rule,'' as defined by 5 U.S.C. 804(2).

Under Executive Order 13771, for each new rule that the Department proposes for notice and comment or otherwise promulgates that is a significant regulatory action under Executive Order 12866, and that imposes total costs greater than zero, it must identify two deregulatory actions. For Fiscal Year 2020, any new incremental costs associated with a new regulation must be fully offset by the elimination of existing costs through deregulatory actions. Because the regulatory action is not significant, the requirements of Executive Order 13771 do not apply.

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

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

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

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

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

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

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

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

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

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

Summary of Costs and Benefits: The Department believes that these final priorities, requirements, definition, and selection criteria will not impose significant costs on the entities eligible to apply for EIR. We also believe that the benefits of implementing the final priorities justify any associated costs.

The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities. Entities selected for awards under section 4611 of the ESEA will be able to pay the costs associated with implementing projects related to teacher-directed professional learning experiences with grant funds. Thus, the costs of these final priorities, requirements, definition, and selection criteria will not be a significant burden for any eligible applicant.

Priority 1 gives the Department the opportunity to elevate the teaching profession by increasing the available funds for professional learning while requiring that applicants maintain current levels of investment. Additionally, by acknowledging teachers' ability to identify their professional learning needs and empowering them to select professional learning opportunities to meet those needs, we believe that this priority could result in a number of changes including reducing personal costs that teachers incur when they must pay for professional learning that they want through their own means if their school, district, or State will not pay for the professional learning. We also believe that teachers are more likely to have a committed investment in professional learning that they select, thereby enhancing the benefits of professional learning, including, but not limited to, increased knowledge and skills. Such changes have the potential to change instructional practices in ways that will improve student outcomes.

Priorities 2 and 3 may have the result of shifting at least some of the Department's grants among eligible entities by giving the Department the opportunity to prioritize partnerships that might be well suited to achieve the purposes of Priority 1. By prioritizing projects that are supported by an SEA or LEA—entities that establish professional development requirements—the Department is increasing the likelihood that such teacher-driven approaches can be implemented more widely, should they be determined as more effective. Because these final priorities would neither expand nor restrict the universe of eligible entities for any Department grant program, and since application submission and participation in our discretionary grant programs is voluntary, there are not costs associated with this priority.

Regulatory Flexibility Act Certification: The Secretary certifies that this final regulatory action will not have a significant economic impact on a substantial number of small entities. The U.S. Small Business Administration Size Standards define ''small entities'' as for-profit or nonprofit institutions with total annual revenue below $7,000,000 or, if they are institutions controlled by small governmental jurisdictions (that are comprised of cities, counties, towns, townships, villages, school districts, or special districts), with a population of less than 50,000.

The small entities that this regulatory action would affect are public or private nonprofit agencies and organizations, including institutions of higher education, that may apply. We believe that the costs imposed on an applicant by the final priorities, requirements, definition, and selection criteria will be limited to paperwork burden related to preparing an application and that the benefits of implementing these final priorities will outweigh any costs incurred by the applicant.

Of the impacts we estimate accruing to grantees or eligible entities, all are voluntary and related mostly to an increase in the availability of teacher-selected professional learning. Therefore, we do not believe that the final priorities, requirements, definition, and selection criteria will significantly impact entities beyond the potential for receiving additional support should the entity receive a competitive grant from the Department.

Paperwork Reduction Act of 1995

As part of its continuing effort to reduce paperwork and respondent burden, the Department provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps ensure that: The public understands the Department's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

The final program priorities, requirements, definition, and selection criteria contain information collection requirements (ICR) for the program application package. As a result of the revisions to these sections, we are submitting the grant application package with OMB control number 1855–0021 for a reinstatement with change. In Table 1 below, we assume 50 applicants each spend 30 hours preparing their applications.

TABLE 1—EIR GRANTS PROGRAM INFORMATION COLLECTION STATUS

OMB control No.	Expiration	Current burden (total hours)	Proposed burden (total hours)	Proposed action under final rule
1855–0021	July 31, 2023	1,500	1,500	Reinstatement with change of 1855–0021.

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

This document provides early notification of our specific plans and actions for this program.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal**

Register by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Frank T. Brogan,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2020–15993 Filed 7–28–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2020–SCC–0122]

Agency Information Collection Activities; Comment Request; Higher Education Emergency Relief Fund (HEERF) Data Collection Form

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before September 28, 2020.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2020–SCC–0122. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance, Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beatriz Ceja, 202–377–3711, or email *heerf@ed.gov.*

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR)6239 that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Higher Education Emergency Relief Fund (HEERF) Data Collection Form.

OMB Control Number: 1840–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local and Tribal Organizations; Private Sector.

Total Estimated Number of Annual Responses: 5,170.

Total Estimated Number of Annual Burden Hours: 7,756.

Abstract: This information collection supports the annual collection of data pertaining to the uses of funds under the Higher Education Emergency Education Relief Fund (HEER Fund). Section 18004(a) of the CARES Act, Public Law 116–136 (March 27, 2020), authorized the Secretary of Education to allocate formula grant funds to participating institutions of higher education (IHEs). Section 18004(c) of the CARES Act allows IHEs to use up to one-half of the total funds received to cover any costs associated with the significant changes to the delivery of instruction due to the coronavirus (with specific exceptions). This information collection request includes the reporting requirements in order to comply with the requirements of the CARES Act and obtain information on how the funds were used. The information will be reviewed by U.S. Department of Education (Department) employees to ensure that HEER funds are used in accordance with section 18004 of the CARES Act, and will be shared with the public to promote transparency regarding the allocation and uses of funds.

HEER Reporting Requirements: Data collected through this information collection will inform Department monitoring and oversight, and public reporting and is in addition to reporting already required under the Federal Funding Accountability and Transparency Act of 2006 (FFATA), Public Law 109—282, as amended by the Digital Accountability and Transparency Act (DATA Act), Public Law 113—101.

HEER Reporting Timeframe: The anticipated reporting periods and associated deadlines for this information collection are as follows:

The First Annual Report is due on January 29, 2021 and applies to the reporting period from March 13, 2020 through June 30, 2020. The Second Annual Report is due on September 30, 2021 and applies to the reporting period from July 1, 2020 through June 30, 2021. The Third Annual Report is due on September 20, 2022 and applies to the reporting period from July 1, 2021 through June 30, 2022.

Directed Questions: The Department requests input from data submitters and stakeholders on the following directed questions. Please note that in addition to these questions, public comments are encouraged on all of the changes proposed. While these questions are directed to IHE data submitters, comments from all stakeholders on these topics are welcome.

(1) What data in this form will be difficult to collect or report and why? Are there changes that could be made to improve the quality of the data or reduce the burden?

(2) The Department believes the data requested under this collection will be valuable for multiple purposes, such as measuring program performance and informing future program design. The Department is interested in learning the extent to which others, particularly stakeholders at the State and local level, agree that this data is valuable for their own purposes and whether there is additional data that would be valuable for the Department to collect from its grantees?

(3) The Department is interested in reducing the burden of data collection and making use of existing data when at all possible. For example, are there

alternative methods to collect data or data that is already collected on institutional expenditures related to HEER funding under section 18004a of the CARES Act?

(4) Will the proposed method for collecting the number of FTE positions created or retained as a result of HEER funds awarded to IHEs yield accurate data? Is there an alternative methodology that would improve the accuracy of the data?

Dated: July 24, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–16429 Filed 7–28–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–1–001]

ANR Pipeline Company; Notice of Application

Take notice that on July 20, 2020, ANR Pipeline Company (ANR), 700 Louisiana Street, Suite 700, Houston, Texas, 77002–2700, filed in Docket No. CP20–1–001 an application for an amendment, pursuant to Section 7(c) of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations, to the certificate of public convenience and necessity issued on March 19, 2020 in this proceeding, relative to the interim lease by ANR of base gas owned by Mid Michigan Gas Storage Company (Mid Michigan) in the Austin, Goodwell, Lincoln-Freeman, Loreed, and Reed City storage fields.

Specifically, ANR seeks authorization to amend the Lease of Base Gas Agreement (Lease Agreement) between ANR and Mid Michigan to reflect changes to certain provisions of Exhibit 1 of the Lease Agreement pertaining to the open season procedures applicable to ANR's base gas purchases, all as more fully described in their application 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 FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202)502–8659.

Any questions concerning this application may be directed to Sorana Linder, Director, Modernization & Certificates, ANR Pipeline Company, 700 Louisiana Street, Suite 700, Houston, Texas, by telephone at (832) 320–5209, or by email at *sorana_linder@tcenergy.com.*

Pursuant to section 157.9 of the Commission's rules (18 CFR 157.9), within 90 days of this Notice, the Commission staff will 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 environmental assessment (EA) for this proposal. 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 EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit seven copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

As of the February 27, 2018 date of the Commission's order in Docket No. CP16–4–001, the Commission will apply its revised practice concerning out-of-time motions to intervene in any new NGA section 3 or section 7 proceeding.[1] Persons desiring to become a party to a certificate proceeding are to intervene in a timely manner. If seeking to intervene out-of-time, the movant is required to ''show good cause why the time limitation should be waived,'' and should provide justification by reference to factors set forth in Rule 214(d)(1) of the Commission's Rules and Regulations.[2]

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFile'' link at *http://www.ferc.gov.* In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426.

[1] *Tennessee Gas Pipeline Company, L.L.C.,* 162 FERC ¶ 61,167 at ¶ 50 (2018).

[2] 18 CFR 385.214(d)(1).

Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern Time on August 13, 2020.

Dated: July 23, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–16423 Filed 7–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2934–029]

New York State Electric & Gas Corporation; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for a new license for the Upper Mechanicville Hydroelectric Project, located on the Hudson River, in Saratoga and Rensselaer Counties, New York, and has prepared an Environmental Assessment (EA) for the project.

The EA contains staff's analysis of the potential environmental impacts of the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The Commission provides all interested persons with an opportunity to view and/or print the EA via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, (202) 502–8659.

You may also register online at *https://ferconline.ferc.gov/eSubscription.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 45 days from the date of this notice.

The Commission strongly encourages electronic filings. Please file comments using the Commission's eFiling system at *https://ferconline.ferc.gov/eFiling.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–2934–029.

For further information, contact Jody Callihan at (202) 502–8278 or by email at *jody.callihan@ferc.gov.*

Dated: July 23, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–16420 Filed 7–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER20–2472–000]

Rancho Seco Solar II LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Rancho Seco Solar II LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 12, 2020.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 23, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–16418 Filed 7–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC20–83–000.

Applicants: GA Solar 3, LLC, Twiggs County Solar, LLC, FL Solar 1, LLC, FL Solar 4, LLC, FL Solar 5, LLC, AZ Solar 1, LLC, Wright Solar Park LLC, Five Points Solar Park LLC, Sunray Energy 2, LLC, Sunray Energy 3 LLC, Three Peaks Power, LLC, Grand View PV Solar Two LLC, Sweetwater Solar, LLC, Techren Solar I LLC, Techren Solar II LLC, Techren Solar III LLC, Techren Solar IV LLC, Techren Solar V LLC, MS Solar 3, LLC, Magnolia Parent LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act, et al. of the GAFG Applicants.

Filed Date: 7/23/20.

Accession Number: 20200723–5054.

Comments Due: 5 p.m. ET 8/13/20.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1633–002.

Applicants: Deseret Generation and Transmission Co-operative, Inc.

Description: Second Supplement to July 26, 2019 Updated Market Power Analysis of Deseret Generation and Transmission Co-operative, Inc.

Filed Date: 7/23/20.

Accession Number: 20200723–5085.

Comments Due: 5 p.m. ET 8/13/20.

Docket Numbers: ER10–3066–004; ER10–2309–006; ER10–3059–004; ER10–3058–004; ER10–3065–004.

Applicants: Edgewood Energy, LLC, Elwood Energy LLC, Equus Power I, L.P., Pinelawn Power, LLC, Shoreham Energy, LLC.

Description: Triennial Market Power Update for the Northeast Region of the J–POWER North America Holdings Co., Ltd. affiliates, et al.

Filed Date: 7/22/20.

Accession Number: 20200722–5172.

Comments Due: 5 p.m. ET 9/21/20.

Docket Numbers: ER20–136–002.

Applicants: Reading Wind Energy, LLC.

Description: Notice of Non-Material Change in Status of Reading Wind Energy, LLC.

Filed Date: 7/10/20.

Accession Number: 20200710–5151.

Comments Due: 5 p.m. ET 7/31/20.

Docket Numbers: ER20–1505–001.

Applicants: Basin Electric Power Cooperative, Inc.

Description: Notice of Change in Status of Basin Electric Power Cooperative.

Filed Date: 7/23/20.

Accession Number: 20200723–5084.

Comments Due: 5 p.m. ET 8/13/20.

Docket Numbers: ER20–2313–000.

Applicants: Boiling Springs Wind Farm, LLC.

Description: Supplement to July 2, 2020 Boiling Springs Wind Farm, LLC tariff filing.

Filed Date: 7/23/20.

Accession Number: 20200723–5062.

Comments Due: 5 p.m. ET 8/3/20.

Docket Numbers: ER20–2485–000.

Applicants: Avista Corporation.

Description: § 205(d) Rate Filing: Avista Corp. KEC Rimrock Construction Agreement SA T1165 to be effective 7/23/2020.

Filed Date: 7/22/20.

Accession Number: 20200722–5125.

Comments Due: 5 p.m. ET 8/12/20.

Docket Numbers: ER20–2486–000.

Applicants: Northern States Power Company, a Minnesota corporation.

Description: § 205(d) Rate Filing: 2020–07–22 NSP–SHKP–SISA–679–0.0.0 to be effective 9/20/2020.

Filed Date: 7/22/20.

Accession Number: 20200722–5129.

Comments Due: 5 p.m. ET 8/12/20.

Docket Numbers: ER20–2487–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: Modifications to PWRPA IA and SAs to Extend Term (WDT SA 56) to be effective 9/23/2020.

Filed Date: 7/22/20.

Accession Number: 20200722–5149.

Comments Due: 5 p.m. ET 8/12/20.

Docket Numbers: ER20–2488–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2020–07–23_SA 3096 Point Beach Solar-ATC (J505) to be effective 7/9/2020.

Filed Date: 7/23/20.

Accession Number: 20200723–5025.

Comments Due: 5 p.m. ET 8/13/20.

Docket Numbers: ER20–2489–000.

Applicants: ISO New England Inc., NSTAR Electric Company.

Description: § 205(d) Rate Filing: ISO–NE & NSTAR; Service Agreement No. LGIA–ISONE/NSTAR–20–01 (Vineyard Wind) to be effective 7/10/2020.

Filed Date: 7/23/20.

Accession Number: 20200723–5038.

Comments Due: 5 p.m. ET 8/13/20.

Docket Numbers: ER20–2490–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of IISA, SA No. 2860; Queue No. V1–026/V1–027 to be effective 7/6/2020.

Filed Date: 7/23/20.

Accession Number: 20200723–5047.

Comments Due: 5 p.m. ET 8/13/20.

Docket Numbers: ER20–2491–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 2891R6 AECC, Entergy Arkansas & MISO Att AO Cancellation to be effective 3/31/2020.

Filed Date: 7/23/20.

Accession Number: 20200723–5048.

Comments Due: 5 p.m. ET 8/13/20.

Docket Numbers: ER20–2492–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: SCE Administrative Correction—Revised Rate Schedule No. 424 Exhibits to be effective 1/1/2017.

Filed Date: 7/23/20.

Accession Number: 20200723–5056.

Comments Due: 5 p.m. ET 8/13/20.

Docket Numbers: ER20–2493–000.

Applicants: OTCF, LLC.

Description: Baseline eTariff Filing: OTCF, LLC MBR Tariff Application to be effective 7/24/2020.

Filed Date: 7/23/20.

Accession Number: 20200723–5072.

Comments Due: 5 p.m. ET 8/13/20.

Docket Numbers: ER20–2494–000.

Applicants: Midcontinent Independent System Operator, Inc., Ameren Illinois Company.

Description: § 205(d) Rate Filing: 2020–07–23_SA 3534 Ameren-SIPC Exclusive As-Available Service Agrmt to be effective 9/22/2020.

Filed Date: 7/23/20.

Accession Number: 20200723–5097.

Comments Due: 5 p.m. ET 8/13/20.

Docket Numbers: ER20–2495–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original ISA, SA No. 5687; Queue No. AF1–188 to be effective 6/29/2020.

Filed Date: 7/23/20.

Accession Number: 20200723–5095.

Comments Due: 5 p.m. ET 8/13/20.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES20–49–000.

Applicants: Duquesne Light Company.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Duquesne Light Company.

Filed Date: 7/22/20.

Accession Number: 20200722–0007.

Comments Due: 5 p.m. ET 7/27/20.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF20–1196–000.

Applicants: DBW Power Company, Inc.

Description: Form 556 of DBW Power Company, Inc.

Filed Date: 7/22/20.

Accession Number: 20200722–5180.

Comments Due: Non-Applicable.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 23, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–16419 Filed 7–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL20–58–000]

American Electric Power Service Corporation; Notice of Petition for Declaratory Order

Take notice that on July 22, 2020, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(2) (2019), American Electric Power Service Corporation (AEP or Petitioner) on behalf of its affiliate, Kentucky Power Company (KPCo, and with other affiliates discussed herein, AEP), hereby submits a petition for declaratory order (Petition) seeking confirmation that the Middle Creek energy storage project, a transmission asset that has undergone full review through the PJM Interconnection, L.L.C. stakeholder process, is eligible for cost-of-service recovery through AEP's Commission-approved transmission formula rates, and specifically through the transmission accounts designated for such projects in Order No. 784,[1] as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

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.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern time on August 21, 2020.

[1] Third-Party Provision of Ancillary Services; Accounting and Financial Reporting for New Elec. Storage Techs., Order No. 784, FERC Stats. & Regs. ¶ 31,349, PP 122–41 (2013), order on clarification, Order No. 784–A, 146 FERC ¶ 61,114 (2014).

Dated: July 23, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–16412 Filed 7–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD20–18–000]

Offshore Wind Integration in RTOs/ISOs; Supplemental Notice of Technical Conference

On June 17, 2020, the Commission issued a notice in the above-captioned proceeding and provided self-nomination instructions for those wishing to participate as panelists. However, due to unforeseen circumstances, the self-nomination form is not accepting submissions. Therefore, in this supplemental notice,[1] we request that individuals interested in participating as panelists—including individuals who used the web-based form prior to the date of this notice—submit their self-nominations by Friday, August 14, 2020 at 5:00 p.m., via email to Ben Foster, *ben.foster@ferc.gov,* and to Sarah McKinley, *sarah.mckinley@ferc.gov.*

The subject line of your email should specify, ''Speaker nomination for Offshore Wind Integration Technical Conference.'' Please include the following information in your nomination:

- First name
- Last name
- Title
- Company or organization
- Address
- City, State, and Zip Code
- Email address
- Telephone number
- Whether you are speaking on behalf of an organization
- Speaker bio (1–2 paragraphs)
- Topic(s) to be addressed

For more information, please contact Ben Foster, 202–502–6149, *ben.foster@ferc.gov,* or Sarah McKinley, 202–502–8368, *sarah.mckinley@ferc.gov.*

Dated: July 17, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–15976 Filed 7–28–20; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 2.1(a)(1)(xi) (2019).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2955–011]

City of Watervliet; Notice of Application Accepted for Filing and Soliciting Motions To Intervene and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* 2955–011.

c. *Date Filed:* February 28, 2020.

d. *Applicant:* City of Watervliet, New York.

e. *Name of Project:* Normanskill Hydroelectric Project.

f. *Location:* The project is located on the Normans Kill in Guilderland, Albany County, New York. The project does not occupy any federal land.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)–825 (r).

h. *Applicant Contact:* Michele E. Stottler, Gomez and Sullivan Engineers, DPC, 399 Albany Shaker Road, Suite 203, Loudonville, NY 12211; (518) 407–0050; email—*mstottler@gomezandsullivan.com* or Joseph LaCivita, General Manager, The City of Watervliet, 2 Fifteenth Street, Watervliet, NY 12189; (518) 270–3800; email—*jlacivita@watervliet.com*.

i. *FERC Contact:* Woohee Choi at (202) 502–6336; or email at *woohee.choi@ferc.gov*.

j. Deadline for filing motions to intervene and protests: 60 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file motions to intervene and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–2955–011.

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 but is not ready for environmental analysis at this time.

l. The Normanskill Project consists of the following existing facilities: (1) A 380-foot-long reinforced concrete Ambursen-type dam with a 306-foot-long overflow section having a crest elevation of 259 feet National Geodetic Vertical Datum of 1929 (NGVD29) surmounted by 3-foot-high flashboards; (2) a 380-acre reservoir with a gross volume of 3,600 acre-feet at the normal maximum pool elevation of 262 feet NGVD29; (3) an intake structure and sluiceway; (4) a 700-foot-long, 6-foot-diameter, concrete-encased steel, buried penstock; (5) a reinforced concrete underground powerhouse containing a single 1,250-kilowatt tube-type generating unit; (6) a 600-foot-long, 2.4-kilovolt (kV) transmission line; (7) a 2.4/13.2-kV transformer bank; and (8) appurtenant facilities.

The Normanskill Project is operated in a run-of-river mode with an average annual generation of 2,863 megawatt-hours between 2010 and 2019.

m. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested individuals an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*www.ferc.gov*) using the ''eLibrary'' link. At this time, the Commission has suspended access to the Commission's Public Access Room due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TTY, (202) 502–8659.

You may also 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 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 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'' or ''MOTION TO INTERVENE;'' (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. 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.

o. Procedural schedule and final amendments: The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Issue Scoping Document 1 for comments	August 2020.
Request Additional Information (if necessary)	October 2020.
Issue Scoping Document 2 (if necessary)	November 2020.
Issue notice of ready for environmental analysis	November 2020.
Commission issues EA	May 2021.
Comments on EA	June 2021.

p. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: July 23, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–16417 Filed 7–28–20; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

[OMB No. 3064–0092]

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collection described below (OMB Control No. 3064–0092).

DATES: Comments must be submitted on or before September 28, 2020.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *https://www.FDIC.gov/regulations/laws/federal.*
- *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 NW, building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

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:* Community Reinvestment Act.

OMB Number: 3064–0092.

Form Number: None.

Affected Public: Insured state nonmember banks and state savings associations.

BURDEN ESTIMATE

Source and type of burden	Description	Estimated number of respondents	Average estimated time per response	Total estimated annual burden
345.25(b) *Reporting*	*Request for designation as a wholesale or limited purpose bank*—Banks requesting this designation shall file a request in writing with the FDIC at least 3 months prior to the proposed effective date of the designation.	1	4	4
345.27 *Reporting*	*Strategic plan*—Applies to banks electing to submit strategic plans to the FDIC for approval.	10	400	4,000
345.42(b)(1) *Reporting*	*Small business/small farm loan data*—Large banks shall and Small banks may report annually in machine readable form the aggregate number and amount of certain loans.	277	8	2,216
345.42(b)(2) *Reporting*	*Community development loan data*—Large banks shall and Small banks may report annually, in machine readable form, the aggregate number and aggregate amount of community development loans originated or purchased.	277	13	3,601
345.42(b)(3) *Reporting*	*Home mortgage loans*—Large banks, if subject to reporting under part 203 (Home Mortgage Disclosure (HMDA)), shall, and Small banks may report the location of each home mortgage loan application, origination, or purchase outside the MSA in which the bank has a home/branch office.	357	253	90,321
345.42(d) *Reporting*	*Data on affiliate lending*—Banks that elect to have the FDIC consider loans by an affiliate, for purposes of the lending or community development test or an approved strategic plan, shall collect, maintain and report the data that the bank would have collected, maintained, and reported pursuant to §345.42(a), (b), and (c) had the loans been originated or purchased by the bank. For home mortgage loans, the bank shall also be prepared to identify the home mortgage loans reported under HMDA.	311	38	11,818
345.42(e) *Reporting*	*Data on lending by a consortium or a third party*—Banks that elect to have the FDIC consider community development loans by a consortium or a third party, for purposes of the lending or community development tests or an approved strategic plan, shall report for those loans the data that the bank would have reported under §345.42(b)(2) had the loans been originated or purchased by the bank.	103	17	1,751
345.42(g) *Reporting*	*Assessment area data*—Large banks shall and Small banks may collect and report to the FDIC a list for each assessment area showing the geographies within the area.	380	2	760
Total Reporting				114,471
345.42(a) *Recordkeeping*	*Small business/small farm loan register*—Large banks shall and Small banks may collect and maintain certain data in machine-readable form.	380	219	83,220
345.42(c) *Recordkeeping*	*Optional consumer loan data*—All banks may collect and maintain in machine readable form certain data for consumer loans originated or purchased by a bank for consideration under the lending test.	10	26	3,260
345.42(c)(2) *Recordkeeping*	*Other loan data*—All banks optionally may provide other information concerning their lending performance, including additional loan distribution data.	103	25	2,575
Total Recordkeeping				89,055

BURDEN ESTIMATE—Continued

Source and type of burden	Description	Estimated number of respondents	Average estimated time per response	Total estimated annual burden
345.41(a) 345.43(a); (a)(1); (a)(2); (a)(3); (a)(4); (a)(5); (a)(6); (a)(7); (b)(1); (b)(2); (b)(3); (b)(4); (b)(5); (c); (d) *Disclosure.*	*Content and availability of public file*—All banks shall maintain a public file that contains certain required information.	3,309	10	33,090
Total Disclosure				33,090
Total Estimated Annual Burden.				236,616 hours

General Description of Collection: The Community Reinvestment Act regulation requires the FDIC to assess the record of banks and thrifts in helping meet the credit needs of their entire communities, including low- and moderate-income neighborhoods, consistent with safe and sound operations; and to take this record into account in evaluating applications for mergers, branches, and certain other corporate activities.

There is no change in the method or substance of the collection. The overall decrease in burden hours is a result of the decrease in the estimated number of respondents.

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.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on July 23, 2020.

James P. Sheesley,

Acting Assistant Executive Secretary.

[FR Doc. 2020–16392 Filed 7–28–20; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS20–07]

Appraisal Subcommittee; Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of special meeting.

Description: In accordance with Section 1104 (b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in open session for a Special Meeting:

Location: Due to the COVID–19 Pandemic, the meeting will be open to the public via live webcast only. Visit the agency's homepage (*www.asc.gov*) and access the provided registration link in the What's New box. You MUST register in advance to attend this Meeting.

Date: July 29, 2020.

Time: 4:00 p.m.

Status: *Open.*

Action and Discussion Items: North Dakota Request to Extend Commercial Temporary Waiver Relief.

How to Attend and Observe an ASC meeting: Due to the COVID–19 Pandemic, the meeting will be open to the public via live webcast only. Visit the agency's homepage (*www.asc.gov*) and access the provided registration link in the What's New box. The meeting space is intended to accommodate public attendees. However, if the space will not accommodate all requests, the ASC may refuse attendance on that reasonable basis. The use of any video or audio tape recording device, photographing device, or any other electronic or mechanical device designed for similar purposes is prohibited at ASC meetings.

James R. Park,

Executive Director.

[FR Doc. 2020–16425 Filed 7–28–20; 8:45 am]

BILLING CODE 6700–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than August 28, 2020.

A. *Federal Reserve Bank of Richmond* (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23219. Comments can also be sent electronically to or *Comments.applications@rich.frb.org*:

1. *Bay-Vanguard, M.H.C., Inc., and BV Financial, Inc., both of Sparrows Point, Maryland;* to acquire Delmarva Bancshares, Inc., and thereby indirectly acquire 1880 Bank, both of Cambridge, Maryland.

B. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Woodforest Financial Group Employee Stock Ownership Plan (with 401(k) Provisions) and the related Woodforest Financial Group Employee Stock Ownership Trust, both of The Woodlands, Texas;* to acquire up to 32 percent of the voting shares of Woodforest Financial Group, Inc., and thereby indirectly acquire Woodforest National Bank, both of The Woodlands, Texas.

Board of Governors of the Federal Reserve System, July 24, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–16413 Filed 7–28–20; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than August 13, 2020.

A. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Barkat Ali, Mike Farhat, both of Southlake, Texas; Kevin Johnston, Pantego, Texas; Judy Han, Wea Lee, both of Houston, Texas; Young Yoo, Clinton Dunn, both of Dallas, Texas; Jeung-Ho Park, Irving, Texas; Andrew Park, Santa Clarita, California; and Mihir Patel, Coppell, Texas;* as a group acting in concert, to acquire voting shares of Riverbend Financial Corporation, and indirectly acquire voting shares of Spectra Bank, both of Fort Worth, Texas.

Board of Governors of the Federal Reserve System, July 24, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–16437 Filed 7–28–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0090; Docket No. 2020–0053; Sequence No. 5]

Information Collection; Rights in Data and Copyrights

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, and the Office of Management and Budget (OMB) regulations, DoD, GSA, and NASA invite the public to comment on a revision and renewal concerning rights in data and copyrights. DoD, GSA, and NASA invite comments on: Whether the proposed collection of information is necessary for the proper performance of the functions of Federal Government acquisitions, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. OMB has approved this information collection for use through October 31, 2020. DoD, GSA, and NASA propose that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: DoD, GSA, and NASA will consider all comments received by September 28, 2020.

ADDRESSES: DoD, GSA, and NASA invite interested persons to submit comments on this collection through *http://www.regulations.gov* and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.*

Instructions: All items submitted must cite Information Collection 9000–0090, Rights in Data and Copyrights. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Zenaida Delgado, Procurement Analyst, at telephone 202–969–7207, or *zenaida.delgado@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0090, Rights in Data and Copyrights.

B. Need and Uses

Contracts must contain terms that delineate the appropriate rights and obligations of the Government and the contractor regarding the use, reproduction and disclosure of data. This clearance covers the information that offerors and contractors must submit to comply with the following Federal Acquisition Regulation (FAR) requirements:

- *FAR 52.227–15, Representation of Limited Rights Data and Restricted Computer Software.* This provision requires an offeror to state, in response to a solicitation, whether data proposed for fulfilling the data delivery requirements qualifies as limited rights

data or restricted computer software. If the Government does not receive unlimited rights, the offeror must provide a list of the data that qualify as limited rights data or restricted computer software. The offeror would identify any proprietary data it would use during contract performance, in order that the contracting officer might ascertain if such proprietary data should be delivered.

• *FAR 52.227–16, Additional Data Requirements.* This clause requires contractors to keep, for possible delivery to the Government, any data, in addition to data already required to be delivered under the contract, first produced or specifically used in performance of the contract for a period of three years from the final acceptance of all items delivered under the contract. The data delivered under this clause may be in the form of computations, preliminary data, records of experiments, etc. For any data to be delivered under this clause, the Government will pay the contractor for converting the data into a specific form, and for reproducing and delivering the data. The purpose of such recordkeeping requirements is to ensure that, if all data requirements are not known prior to contract award, the Government can fully evaluate the research in order to ascertain future activities and to insure that the research was completed and fully reported, as well as to give the public an opportunity to assess the research results and secure any additional information.

• *FAR 52.227–17, Rights in Data-Special Works.* This clause is included in solicitations and contracts primarily for production or compilation of data. It is used in rare and exceptional circumstances to permit the Government to limit the contractor's rights in data by preventing the release, distribution, and publication of any data first produced in the performance of the contract. This clause may also be limited to particular items and not the entire contract. This clause requires contractors to assign (with or without registration), or obtain the assignment of, the copyright to the Government or its designated assignee.

• *FAR 52.227–18, Rights in Data-Existing Works.* This clause is used when the Government is acquiring existing audiovisual or similar works, such as books, without modification. This clause requires contractors to obtain license for the Government to reproduce, prepare derivative works, and perform and display publicly the materials.

• *FAR 52.227–19, Commercial Computer Software License.* This clause requires contractors to affix a notice on any commercial software delivered under the contract that provides notice that the Government's rights regarding the data are set forth in the contract.

• *FAR 52.227–20, Rights in Data–SBIR Program.* This clause authorizes contractors under Small Business Innovation Research (SBIR) contracts to affix a notice to SBIR data delivered under the contract to limit the Government's rights to disclose data first produced under the contract. Contractors shall obtain from their subcontractors all data and rights necessary to fulfill the contractor's obligations to the Government under the contract. If a subcontractor refuses to accept terms affording the Government those rights, the contractor shall notify the contracting officer of the refusal.

• *FAR 52.227–21, Technical Data Declaration, Revision, and Withholding of Payment–Major Systems.* This clause requires major systems contractors to certify that the data delivered under the contract is complete, accurate, and compliant with the requirements of the contract.

• *FAR 52.227–23, Rights to Proposal Data (Technical).* This clause allows the Government to identify pages of a proposal that would not be subject to unlimited rights in the technical data.

C. Annual Burden

Respondents/Recordkeepers: 2,106.
Total Annual Responses: 5,999.
Total Burden Hours: 5,999. (1,403 reporting hours + 4,596 recordkeeping hours).

Obtaining Copies

Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 9000–0090, Rights in Data and Copyrights.

William F. Clark,

Director, Office of Government-Wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2020–16402 Filed 7–28–20; 8:45 am]

BILLING CODE 6820–EP–P

OFFICE OF GOVERNMENT ETHICS

Announcement of Office of Government Ethics Guidance Portal

AGENCY: Office of Government Ethics.

ACTION: Notice of new guidance portal.

SUMMARY: The U.S. Office of Government Ethics (OGE) is publishing this notice to announce a new guidance portal on its website for guidance documents, as required by Executive Order 13891 ''Promoting the Rule of Law Through Improved Agency Guidance Documents.''

DATES: The guidance portal is accessible by the public on the date of publication of this notice: July 29, 2020.

FOR FURTHER INFORMATION CONTACT: Patrick J. Lightfoot, Assistant Counsel, U.S. Office of Government Ethics, Telephone: 202–482–9300.

SUPPLEMENTARY INFORMATION: Executive Order 13891 ''Promoting the Rule of Law Through Improved Agency Guidance Documents'' requires each agency to establish or maintain on its website a guidance portal that contains or links to all guidance documents in effect issued by that agency. Guidance documents are defined by the Executive Order, subject to certain exclusions, as agency statements of general applicability, intended to have future effect on the behavior of regulated parties, that set forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation.

The Office of Management and Budget (OMB) issued Memorandum M–20–02, ''Guidance Implementing Executive Order 13891, Titled 'Promoting the Rule of Law Through Improved Agency Guidance Documents' '' on October 31, 2019. OMB's memorandum directed agencies to establish a guidance portal and publish a notice in the **Federal Register** announcing it. Accordingly, this notice announces that OGE has established its guidance portal at: *https://www.oge.gov/guidance.*

The guidance portal notes that guidance documents do not have the force and effect of law, except as authorized by law or as incorporated into a contract. However, to the extent that a guidance document provides an interpretation of the government ethics laws and regulations or concerns aspects of ethics program management, guidance documents are controlling within the executive branch. Guidance documents not included in the guidance portal will not be cited to, used, or relied on by OGE, except to establish historical facts.

Approved: July 23, 2020.

Emory Rounds,

Director, U.S. Office of Government Ethics.

[FR Doc. 2020–16363 Filed 7–28–20; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3388–FN]

Medicare and Medicaid Programs; Application From DNV GL Healthcare USA Inc. for Initial CMS Approval of Its Psychiatric Hospital Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve DNV GL Healthcare USA Inc. (DNV GL) for initial recognition as a national accrediting organization for psychiatric hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this final notice is effective July 30, 2020 through July 30, 2024.

FOR FURTHER INFORMATION CONTACT: Joann Fitzell, (410) 786–4280. Lillian Williams, (410) 786–8636.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a psychiatric hospital provided certain requirements established by the Secretary of the Department of Health and Human Services (the Secretary) are met. Section 1861(f) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a psychiatric hospital under Medicare. Regulations concerning provider agreements and supplier approval are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 482 subparts A, B, C and E specify the minimum conditions that a psychiatric hospital must meet to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for psychiatric hospitals.

Generally, to enter into a provider agreement with the Medicare program, a psychiatric hospital must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 482 subpart A, B, C and E of Centers for Medicare & Medicaid Services (CMS) regulations. Thereafter, the psychiatric hospital is subject to regular surveys by a state survey agency to determine whether it continues to meet the Medicare requirements.

However, there is an alternative to surveys by state agencies. Section 1865(a)(1) of the Act states, if a provider entity demonstrates through accreditation by an approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we may treat the provider entity as having met those conditions, that is, we may deem the provider entity as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by CMS as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at § 488.5. The regulations at § 488.5(e)(2)(i) require the AO to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

II. Application Approval Process

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that findings concerning review and approval of an AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities that were found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides CMS 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, CMS must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, CMS must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

On March 2, 2020 **Federal Register** (85 FR 12306), we published a proposed notice announcing DNV GL Healthcare USA Inc. (DNV GL) request for approval of its Medicare psychiatric hospital accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of DNV GL's Medicare psychiatric hospital accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of DNV GL's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its psychiatric hospital surveyors; (4) ability to investigate and respond appropriately to complaints against accredited psychiatric hospitals; and, (5) survey review and decision-making process for accreditation.
- The comparison of DNV GL's Medicare psychiatric hospital accreditation program standards to our current Medicare hospitals Conditions of Participation (CoPs) and psychiatric hospital special CoPs.
- A documentation review of DNV GL's psychiatric hospital survey process to do the following:

++ Determine the composition of the survey team, surveyor qualifications, and DNV GL's ability to provide continuing surveyor training.

++ Compare DNV GL's processes to those we require of state survey agencies, including periodic re-survey and the ability to investigate and respond appropriately to complaints against accredited psychiatric hospitals.

++ Evaluate DNV GL's procedures for monitoring psychiatric hospitals it has found to be out of compliance with DNV GL's program requirements. (This pertains only to monitoring procedures when DNV GL identifies as non-compliance. If noncompliance is identified by a state survey agency through a validation survey, the state survey agency monitors corrections as specified at § 488.9(c)(1)).

++ Assess DNV GL's ability to report deficiencies to the surveyed hospital and respond to the psychiatric hospital's plan of correction in a timely manner.

++ Establish DNV GL's ability to provide CMS with electronic data and reports necessary for effective validation

and assessment of the organization's survey process.

++ Determine the adequacy of DNV GL's staff and other resources.

++ Confirm DNV GL's ability to provide adequate funding for performing required surveys.

++ Confirm DNV GL's policies with respect to surveys being unannounced.

++ Confirm DNV GL's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ Obtain DNV GL's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

++ As authorized under § 488.8(h), CMS reserves the right to conduct onsite observations of accrediting organization's operations at any time as part of the ongoing review and continuing oversight of an AO's performance.

In accordance with section 1865(a)(3)(A) of the Act, the March 2, 2020 proposed notice also solicited public comments regarding whether DNV GL's requirements met or exceeded the Medicare CoPs for psychiatric hospitals. We received 4 comments in response to our proposed notice. We thank the commenters for their support. We agreed with the commenters that a new psychiatric hospital accreditation organization would provide hospitals further options in regards to accreditation. Based on our comprehensive review of their program, we have approved DNV GL as such a program.

IV. Provisions of the Final Notice

A. Differences Between DNV GL's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared DNV GL's psychiatric hospital accreditation program requirements and survey process with the Medicare CoPs at 42 CFR part 482, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of DNV GL's psychiatric hospital application, which were conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, DNV GL has revised its standards and certification processes in order to meet the requirements at:

- *Section 482.41(c)(1):* DNV GL revised its standards to not require the hospitals to adopt Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code.
- *Section 482.61(a) through (a)(3):* DNV GL revised its standards to require a diagnosis for all patients.
- *Section 482.61(b):* DNV GL revised its standards to require a record of mental status.
- *State Operations Manual Chapter 3 Section 3012:* DNV GL revised its materials to reflect its timeframe(s) for follow-up activities, including follow-up surveys for facilities that have previously demonstrated non-compliance at the condition level.
- *Section 488.5(a)(12):* DNV GL revised its policies to ensure a clearly defined complaint investigation process is in place that meets the requirements in the State Operations Manual Chapter 5 Section 5010 and Chapter 5 Section 5075.2 that includes the following:

++ Complete and accurate tracking of complaints as well as a process for maintaining a documented record of contacts made (for example, phone, email and United States mail) with the complainant, and others, if applicable.

++ Defining the number of contact attempts required before closing out a complaint if the complainant does not respond.

++ Educating DNV GL complaint intake staff that when complaint allegations could potentially result in condition-level non-compliance affecting the health and safety of patients, a survey is to be considered regardless if the allegation also involves payment related allegations.

++ Investigating complaints onsite within an appropriate timeframe.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that DNV GL's psychiatric hospital accreditation program requirements meet or exceed our requirements, and its survey processes are also comparable. Therefore, we approve DNV GL as a national AO for psychiatric hospitals that request participation in the Medicare program, effective July 30, 2020 through July 30, 2024.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: July 24, 2020.

Lynette Wilson,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020–16453 Filed 7–28–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1339]

Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff.'' This final guidance provides FDA's regulatory approach for device products with multiple functions including at least one device function and includes such device products that are part of combination products, in accordance with the 21st Century Cures Act (Cures Act).

DATES: The announcement of the guidance is published in the **Federal Register** on July 29, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a

third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

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

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

Instructions: All submissions received must include the Docket No. FDA–2018–D–1339 for ''Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or the Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD 20993–0002, 301–796–5528; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911; or Kristina Lauritsen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6162, Silver Spring, MD 20993–0002, 301–796–8936.

SUPPLEMENTARY INFORMATION:

I. Background

On December 13, 2016, the Cures Act (Pub. L. 114–255) was signed into law. Section 3060(a) of this legislation entitled ''Clarifying Medical Software Regulation'' amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add section 520(o) (21 U.S.C. 360j(o)), which excludes certain software functions from the definition of device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)). In addition, section 520(o)(2) of the FD&C Act describes the regulation and assessment of a product with multiple functions including at least one device function and at least one software function that is not a device. Although section 520(o)(2) of the FD&C Act applies to the regulation of software products containing at least one device function and at least one non-device software function, FDA believes that a similar approach should be used for the assessment of all multiple function device products that contain at least one device function and one ''other function'', which may be a non-device software function; a function that meets the definition of a device, but is not subject to premarket review; or a function that meets the definition of device, but for which FDA has expressed its intention not to enforce compliance with applicable regulatory controls. This approach also applies to multiple function device products that are device constituent parts of combination products. FDA considered comments received on the draft guidance that appeared in the **Federal Register** of April 27, 2018 (83 FR 18570). FDA revised the guidance as appropriate in response to the comments.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17038 to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information have been approved by OMB as follows:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
803	Medical device reporting	0910–0437
807, subparts A through D	Registration and listing	0910–0625
807, subpart E	Premarket notification	0910–0120
812	Investigational device exemption	0910–0078
814, subparts A through E	Premarket approval applications	0910–0231
814, subpart H	Humanitarian use devices	0910–0332
820	Current good manufacturing practice and the quality system regulation.	0910–0073
312	Investigational New Drug Regulations	0910–0014
314	Applications for FDA Approval to Market a New Drug	0910–0001
314	Abbreviated New Drug Applications and 505(b)(2) Applications	0910–0786
601; Form FDA 356h	Biologics License; Application to Market a New Drug or Abbreviated New Drug or Biologic for Human Use—Form FDA 356h.	0910–0338
''User Fees for 513(g) Requests for Information'' and ''FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act''.	513(g) requests	0910–0705
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo requests	0910–0844

Dated: July 23, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16394 Filed 7–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0008]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on September 8, 2020, from 8 a.m. to 6 p.m. Eastern Time and on September 9, 2020, from 8 a.m. to 1 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform held via webcast only. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* The meeting will be webcast both days and will be available at the following link:

Webcast link for Day 1: http://fda.yorkcast.com/webcast/Play/8ef8ac6b36f244beaced2a3031eebc621d.

Webcast link for Day 2: http://fda.yorkcast.com/webcast/Play/0e1b175674de4b1e8a4675cf5096aa601d.

FOR FURTHER INFORMATION CONTACT: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993–0002, *Patricio.Garcia@fda.hhs.gov,* 301–796–6875, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On September 8, 2020, during session 1, the committee will discuss and make recommendations regarding the classification of facet screws systems which are currently unclassified pre-amendment devices to Class II (general and special controls). During session II, the committee will discuss and make

recommendations regarding the reclassification of non-invasive bone growth stimulators which are currently post-amendment devices from Class III (general controls and premarket approval) to Class II (general and special controls).

On September 9, 2020, the committee will discuss and make recommendations regarding the classification of three devices, which are currently unclassified pre-amendment devices to class II (general and special controls). The committee, during session I, will discuss semi-constrained toe (metatarsophalangeal) joint prostheses; during session II, will discuss intracompartmental pressure monitors; and during session III, will discuss intra-abdominal pressure monitoring devices.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/orthopaedic-and-rehabilitation-devices-panel.*

Select the link for the 2020 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 28, 2020. Oral presentations from the public will be scheduled on September 8, 2020 between approximately 8:15 a.m. and 8:45 a.m. and between approximately 1 p.m. and 1:30 p.m.; on September 9, 2020, between approximately 8:15 a.m. and 9:15 a.m. Those individuals interested in making formal oral presentations should notify the contact person and indicate during which session they would like to present (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 20, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing sessions. The contact person will notify interested persons regarding their request to speak by August 21, 2020.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallet at *artair.mallett@fda.hhs.gov* or 301–796–9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 23, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16436 Filed 7–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1294]

Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biological Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biological Products.'' This guidance describes FDA's current recommendations about endotoxin limits in certain investigational oncology drugs and biological products. This guidance looks at a risk-based approach of weighing the potential risks of not evaluating endotoxin levels in all components of a multidrug regimen against the potential benefits to patients with serious and life-threatening diseases.

DATES: Submit either electronic or written comments on the draft guidance by September 28, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–

2020–D–1294 for ''Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biological Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia Keegan, Center for Drug Evaluation and Research, Food and Drug Administration, 10993 New Hampshire Ave., Bldg. 22, Rm. 2322, Silver Spring, MD 20993, 301–796–1387; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biological Products.'' When finalized, this guidance will describe FDA's current recommendations about endotoxin limits in investigational oncology drugs and biological products. It looks at a risk-based approach of weighing the potential risks of not evaluating endotoxin levels in all components of a multidrug regimen against the potential benefits to patients with serious and life-threatening diseases. It is limited to anticancer drugs administered parenterally (except for intraocular administration) to treat serious and life-threatening cancers based on histology or stage of disease.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biological Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: July 22, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16340 Filed 7–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Request for Information on Innovative Programs To Reconnect Youth to Education and Employment and Promote Self-Sufficiency

AGENCY: Office of the Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: HHS issues this Request for Information (RFI) in order to seek information about programs that provide services to help young people, ages 16 to 24, advance on education and employment pathways. This project is focused on the population of young people who are out of work and/or out of school, particularly those from lower income families and communities, sometimes called disconnected or opportunity youth. The information gathered will result in a public compendium that profiles selected programs operating in this area, particularly innovative programs.

DATES: Submit written comments at the address provided below no later than September 28, 2020.

ADDRESSES: Written comments should be submitted to *ReconnectingYouthRFI@hhs.gov.* HHS encourages the early submission of comments.

FOR FURTHER INFORMATION CONTACT: Lisa Trivits on the Reconnecting Youth team at *ReconnectingYouthRFI@hhs.gov* or 202–205–9256.

SUPPLEMENTARY INFORMATION: *Invitation to Comment:* HHS invites comments

responding to the questions included in this notice. To ensure that your comments are clearly stated, please identify the specific question, or other section of this notice, that your comments address.

1.0 Background

In the fall of 2019, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) within the U.S. Department of Health and Human Services, funded MDRC and its partner, Child Trends, to conduct a project examining practices and programs aimed at reconnecting youth to school and work. This RFI is intended to help identify programs for the first major task of the project, which is to conduct a scan of programs and practices, including innovative approaches, aimed at improving education and employment outcomes for disconnected young people from low-income families and communities. The information gathered through this RFI will result in a public compendium that profiles selected programs operating in this area, particularly innovative programs. To ensure this project reaches the full range of programs operating in the United States, including new and innovative programs, we are seeking recommendations on programs to be screened for inclusion in the compendium. Specifically, we are seeking information about programs that provide services to help youth ages 16 to 24 advance on education and employment pathways.

2.0 Request for Information

Through this RFI, HHS seeks to gather feedback from public stakeholders—state and local government agencies, local program operators, and the people that we serve—to identify programs that aim to improve education and employment outcomes for the population of young people who are out of work and out of school, particularly those from low income families or communities, sometimes called disconnected or opportunity youth. Please note that we will consider all recommended programs, but not all submissions will be included in the compendium.

We are looking for programs that fit the following criteria:

- Serves young people ages 16–24 (may also serve adults).
- Targets young people who are out of school, out of work, or have other risk factors (low income family, or community; parenting; justice involved; foster care; experiencing homelessness; has a disability).
- Provides services in support of education or employment goals.
- Currently operating in the United States.

3.0 Key Questions

Please use the questions below to tell us about programs that you think we should consider for this project.

3.1 What is the program's full name?
3.2 What is the program's website?
3.3 Where does the program operate (city, state, region, or national)?
3.4 Please provide a brief description of the mission and main activities of the program.
3.5 Please indicate yes/no/not sure if the program serves young people with any of the following characteristics:

Yes/No/Not sure
3.5a Ages 16 to 24
3.5b Did not complete high school
3.5c Not currently attending college/postsecondary education
3.5d Low income family/community
3.5e English Language Learners
3.5f Homeless
3.5g In foster care or aged out of foster care
3.5h Pregnant/Parenting
3.5i Involved in the juvenile or criminal justice system
3.5j Has a disability

Dated: July 23, 2020.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation (HSP).

[FR Doc. 2020–16422 Filed 7–28–20; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Deafness and Other Communication Disorders Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space availability. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Deafness and Other Communication Disorders Advisory Council.

Date: September 10–11, 2020.

Closed: September 10, 2020, 12:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NSC, 6001 Executive Blvd., Rockville, MD 20852 (Virtual Meeting).

Open: September 10, 2020, 1:30 p.m. to 4:00 p.m.

Agenda: Staff reports on divisional, programmatical, and special activities.

Place: National Institutes of Health, NSC, 6001 Executive Blvd., Rockville, MD 20852 (Virtual Meeting).

Closed: September 11, 2020, 10:00 a.m. to 10:40 a.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, NSC, 6001 Executive Blvd., Rockville, MD 20852 (Virtual Meeting).

Open: September 11, 2020, 10:40 a.m. to 2:00 p.m.

Agenda: Staff reports on divisional, programmatical, and special activities.

Place: National Institutes of Health, NSC, 6001 Executive Blvd., Rockville, MD 20852 (Virtual Meeting).

Contact Person: Craig A. Jordan, Ph.D., Director, Division of Extramural Activities, NIDCD, NIH, Room 8345, MSC 9670, 6001 Executive Blvd., Bethesda, MD 20892–9670, (301) 496–8693, *jordanc@nidcd.nih.gov*.

Information is also available on the Institute's/Center's home page: *https://www.nidcd.nih.gov/about/advisory-council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: July 23, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–16347 Filed 7–28–20; 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 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: Center for Scientific Review Special Emphasis Panel; RFA–RM–19–012: Enhanced Utility and Usage of Common Fund Data Sets.

Date: August 7, 2020.

Time: 3:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Robert C Elliott, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3130, MSC 7850 Bethesda, MD 20892, 301–435–3009, *elliotro@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 23, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–16390 Filed 7–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Advisory Committee for Women's Services (ACWS); Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the Substance Abuse and Mental Health Services Administration's (SAMHSA) Advisory Committee for Women's Services (ACWS) on August 19, 2020.

The meeting will include discussions on assessing SAMHSA's current strategies, including the mental health and substance use needs of the women and girls population. Additionally, the ACWS will be addressing priorities regarding the impact of COVID–19 on the behavioral health needs of women and children, and the current ethnic/racial climate and related economic and health disparities on women, and directions around behavioral health services and access for women and children.

The meeting is open to the public and will be held virtually only. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Written submissions should be forwarded to the contact person by August 9, 2020. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations must notify the contact person on or before August 9, 2020. Up to five minutes will be allotted for each presentation, as time permits.

The meeting may be accessed via telephone or web meeting. To obtain the call-in number and access code, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register on-line at *http://snacregister.samhsa.gov/MeetingList.aspx*, or communicate with SAMHSA's Designated Federal Officer, Ms. Valerie Kolick.

Substantive meeting information and a roster of ACWS members may be obtained either by accessing the SAMHSA Committees' Web *https://www.samhsa.gov/about-us/advisory-councils/meetings,* or by contacting Ms. Kolick.

Committee Name: Substance Abuse and Mental Health Services Administration, Advisory Committee for Women's Services (ACWS).

Date/Time/Type: Wednesday, August 19, 2020, from: 1:00 p.m. to 4:30 p.m. EDT (OPEN).

Place: SAMHSA, 5600 Fishers Lane, Rockville, MD 20857 (Virtual).

Contact: Valerie Kolick, Designated Federal Officer, SAMHSA's Advisory Committee for Women's Services, 5600 Fishers Lane, Rockville, MD 20857, Telephone: (240) 276–1738, Email: *Valerie.kolick@samhsa.hhs.gov*.

Dated: July 23, 2020.

Carlos Castillo,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 2020–16362 Filed 7–28–20; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 20–14]

COBRA Fees To Be Adjusted for Inflation in Fiscal Year 2021

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces that U.S. Customs and Border Protection (CBP) is adjusting certain customs user fees and corresponding limitations established by the Consolidated Omnibus Budget Reconciliation Act (COBRA) for Fiscal Year 2021 in accordance with the Fixing America's Surface Transportation Act (FAST Act) as implemented by the CBP regulations.

DATES: The adjusted amounts of customs COBRA user fees and their corresponding limitations set forth in this notice for Fiscal Year 2021 are required as of October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Tina Ghiladi, Senior Advisor, International Trade & Travel, Office of Finance, 202–344–3722, *UserFeeNotices@cbp.dhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

A. Adjustments of COBRA User Fees and Corresponding Limitations for Inflation

On December 4, 2015, the Fixing America's Surface Transportation Act (FAST Act, Pub. L. 114–94) was signed into law. Section 32201 of the FAST Act amended section 13031 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (19 U.S.C. 58c) by requiring the Secretary of the Treasury (Secretary) to adjust certain customs COBRA user fees and corresponding limitations to reflect certain increases in inflation.

Sections 24.22 and 24.23 of title 19 of the Code of Federal Regulations (19 CFR 24.22 and 24.23) describe the procedures that implement the requirements of the FAST Act. Specifically, paragraph (k) in section 24.22 (19 CFR 24.22(k)) sets forth the methodology to determine the change in

inflation as well as the factor by which the fees and limitations will be adjusted, if necessary. The fees and limitations subject to adjustment, which are set forth in Appendix A and Appendix B of part 24, include the commercial vessel arrival fees, commercial truck arrival fees, railroad car arrival fees, private vessel arrival fees, private aircraft arrival fees, commercial aircraft and vessel passenger arrival fees, dutiable mail fees, customs broker permit user fees, barges and other bulk carriers arrival fees, and merchandise processing fees, as well as the corresponding limitations.

B. Determination of Whether an Adjustment Is Necessary for Fiscal Year 2021

In accordance with 19 CFR 24.22, CBP must determine annually whether the fees and limitations must be adjusted to reflect inflation. For fiscal year 2021, CBP is making this determination by comparing the average of the Consumer Price Index—All Urban Consumers, U.S. All items, 1982–1984 (CPI–U) for the current year (June 2019–May 2020) with the average of the CPI–U for the comparison year (June 2018–May 2019) to determine the change in inflation, if any. If there is an increase in the CPI–U of greater than one (1) percent, CBP must adjust the customs COBRA user fees and corresponding limitations using the methodology set forth in 19 CFR 24.22(k). Following the steps provided in paragraph (k)(2) of section 24.22, CBP has determined that the increase in the CPI–U between the most recent June to May twelve-month period (June 2019–May 2020) and the comparison year (June 2018–May 2019) is 1.58 [1] percent. As the increase in the CPI–U is greater than one (1) percent, the customs COBRA user fees and corresponding limitations must be adjusted for Fiscal Year 2021.

C. Determination of the Adjusted Fees and Limitations

Using the methodology set forth in section 24.22(k)(2) of the CBP regulations (19 CFR 24.22(k)), CBP has determined that the factor by which the base fees and limitations will be adjusted is 8.933 percent (base fees and limitations can be found in Appendices A and B to part 24 of title 19). In reaching this determination, CBP calculated the values for each variable found in paragraph (k) of 19 CFR 24.22 as follows:

- The arithmetic average of the CPI–U for June 2019–May 2020, referred to as (A) in the CBP regulations, is 257.092;
- The arithmetic average of the CPI–U for Fiscal Year 2014, referred to as (B), is 236.009;
- The arithmetic average of the CPI–U for the comparison year (June 2018–May 2019), referred to as (C), is 252.922;
- The difference between the arithmetic averages of the CPI–U of the comparison year (June 2018–May 2019) and the current year (June 2019–May 2020), referred to as (D), is 4.170;
- This difference rounded to the nearest whole number, referred to as (E), is 4;
- The percentage change in the arithmetic averages of the CPI–U of the comparison year (June 2018–May 2019) and the current year (June 2019–May 2020), referred to as (F), is 1.58 percent;
- The difference in the arithmetic average of the CPI–U between the current year (June 2019–May 2020) and the base year (Fiscal Year 2014), referred to as (G), is 21.084; and
- Lastly, the percentage change in the CPI–U from the base year (Fiscal Year 2014) to the current year (June 2019–May 2020), referred to as (H), is 8.933 percent.

D. Announcement of New Fees and Limitations

The adjusted amounts of customs COBRA user fees and their corresponding limitations for Fiscal Year 2021 as adjusted by 8.933 percent set forth below are required as of October 1, 2020. Table 1 provides the fees and limitations found in 19 CFR 24.22 as adjusted for Fiscal Year 2021, and Table 2 provides the fees and limitations found in 19 CFR 24.23 as adjusted for Fiscal Year 2021.

TABLE 1—CUSTOMS COBRA USER FEES AND LIMITATIONS FOUND IN 19 CFR 24.22 AS ADJUSTED FOR FISCAL YEAR 2021

19 U.S.C. 58c	19 CFR 24.22	Customs COBRA user fee/limitation	New fee/ limitation adjusted in accordance with the FAST act
(a)(1)	(b)(1)(i)	Fee: Commercial Vessel Arrival Fee	$476.04
(b)(5)(A)	(b)(1)(ii)	Limitation: Calendar Year Maximum for Commercial Vessel Arrival Fees	6,486.99
(a)(8)	(b)(2)(i)	Fee: Barges and Other Bulk Carriers Arrival Fee	119.83
(b)(6)	(b)(2)(ii)	Limitation: Calendar Year Maximum for Barges and Other Bulk Carriers Arrival Fees.	1,634.00
(a)(2)	(c)(1)	Fee: Commercial Truck Arrival Fee [2] [3]	5.95
(b)(2)	(c)(2) and (3)	Limitation: Commercial Truck Calendar Year Prepayment Fee [4]	108.93
(a)(3)	(d)(1)	Fee: Railroad Car Arrival Fee	8.99
(b)(3)	(d)(2) and (3)	Limitation: Railroad Car Calendar Year Prepayment Fee	108.93
(a)(4)	(e)(1) and (2)	Fee and Limitation: Private Vessel or Private Aircraft First Arrival/Calendar Year Prepayment Fee.	29.96
(a)(6)	(f)	Fee: Dutiable Mail Fee	5.99
(a)(5)(A)	(g)(1)(i)	Fee: Commercial Vessel or Commercial Aircraft Passenger Arrival Fee	5.99

[1] The figures provided in this notice may be rounded for publication purposes only. The calculations for the adjusted fees and limitations were made using unrounded figures, unless otherwise noted.

[2] The Commercial Truck Arrival Fee is the CBP fee only; it does not include the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Agricultural and Quarantine Inspection (AQI) Services Fee (currently $7.55) that is collected by CBP on behalf of USDA to make a total Single Crossing Fee of $13.50. *See* 7 CFR 354.3(c) and 19 CFR 24.22(c)(1). Once eighteen Single Crossing Fees have been paid and used for a vehicle identification number (VIN)/vehicle in a Decal and Transponder Online Procurement System (DTOPS) account within a calendar year, the payment required for the nineteenth (and subsequent) single-crossing is only the AQI fee (currently $7.55) and no longer includes CBP's $5.95 Commercial Truck Arrival fee (for the remainder of that calendar year).

[3] The Commercial Truck Arrival fee is adjusted down from $5.99 to the nearest lower nickel. *See* 82 FR 50523 (November 1, 2017).

[4] The Commercial Truck Calendar Year Prepayment Fee is the CBP fee only; it does not include the AQI Commercial Truck with Transponder Fee (currently $301.67) that is collected by CBP on behalf of APHIS to make the total Commercial Vehicle Transponder Annual User Fee of $410.60.

TABLE 1—CUSTOMS COBRA USER FEES AND LIMITATIONS FOUND IN 19 CFR 24.22 AS ADJUSTED FOR FISCAL YEAR 2021—Continued

19 U.S.C. 58c	19 CFR 24.22	Customs COBRA user fee/limitation	New fee/ limitation adjusted in accordance with the FAST act
(a)(5)(B)	(g)(1)(ii)	Fee: Commercial Vessel Passenger Arrival Fee (from one of the territories and possessions of the United States).	2.10
(a)(7)	(h)	Fee: Customs Broker Permit User Fee	150.33

TABLE 2—CUSTOMS COBRA USER FEES AND LIMITATIONS FOUND IN 19 CFR 24.23 AS ADJUSTED FOR FISCAL YEAR 2021

19 U.S.C. 58c	19 CFR 24.23	Customs COBRA user fee/limitation	New fee/ limitation adjusted in accordance with the FAST act
(b)(9)(A)(ii)	(b)(1)(i)(A)	Fee: Express Consignment Carrier/Centralized Hub Facility Fee, Per Individual Waybill/Bill of Lading Fee.	$1.09
(b)(9)(B)(i)	(b)(4)(ii)[5]	Limitation: Minimum Express Consignment Carrier/Centralized Hub Facility Fee[6]	0.38
(b)(9)(B)(i)	(b)(4)(ii)[7]	Limitation: Maximum Express Consignment Carrier/Centralized Hub Facility Fee	1.09
(a)(9)(B)(i); (b)(8)(A)(i)	(b)(1)(i)(B)[8]	Limitation: Minimum Merchandise Processing Fee[9]	27.23
(a)(9)(B)(i); (b)(8)(A)(i)	(b)(1)(i)(B)[10]	Limitation: Maximum Merchandise Processing Fee[11 12]	528.33
(b)(8)(A)(ii)	(b)(1)(ii)	Fee: Surcharge for Manual Entry or Release	3.27
(a)(10)(C)(i)	(b)(2)(i)	Fee: Informal Entry or Release; Automated and Not Prepared by CBP Personnel	2.18
(a)(10)(C)(ii)	(b)(2)(ii)	Fee: Informal Entry or Release; Manual and Not Prepared by CBP Personnel	6.54
(a)(10)(C)(iii)	(b)(2)(iii)	Fee: Informal Entry or Release; Automated or Manual; Prepared by CBP Personnel.	9.80
(b)(9)(A)(ii)	(b)(4)	Fee: Express Consignment Carrier/Centralized Hub Facility Fee, Per Individual Waybill/Bill of Lading Fee.	1.09

Tables 1 and 2, setting forth the adjusted fees and limitations for Fiscal Year 2021, will also be maintained for the public's convenience on the CBP website at *www.cbp.gov.*

Dated: July 24, 2020.

Mark A. Morgan,

Chief Operating Officer and Senior Official Performing the Duties of the Commissioner, U.S. Customs and Border Protection.

[FR Doc. 2020–16450 Filed 7–28–20; 8:45 am]

BILLING CODE 9111–14–P

[5] Appendix B of part 24 inadvertently included a reference to paragraph (b)(1)(i)(B)(2) of section 24.23. However, the reference should have been to paragraph (b)(4)(ii). CBP intends to publish a future document in the **Federal Register** to make a technical correction to Appendix B of part 24. This technical correction will also address the inadvertent errors specified in footnotes 7, 8, and 10 below.

[6] Although the minimum limitation is published, the fee charged is the fee required by 19 U.S.C. 58c(b)(9)(A)(ii).

[7] Appendix B of part 24 inadvertently included a reference to paragraph (b)(1)(i)(B)(2) of section 24.23. However, the reference should have been to paragraph (b)(4)(ii).

[8] Appendix B of part 24 inadvertently included a reference to paragraph (b)(1)(i)(B)(1) of section 24.23. However, the reference should have been to paragraph (b)(1)(i)(B).

[9] Only the limitation is increasing; the *ad valorem* rate of 0.3464 percent remains the same. *See* 82 FR 50523 (November 1, 2017).

[10] Appendix B of part 24 inadvertently included a reference to paragraph (b)(1)(i)(B)(1) of section 24.23. However, the reference should have been to paragraph (b)(1)(i)(B).

[11] Only the limitation is increasing; the *ad valorem* rate of 0.3464 percent remains the same. *See* 82 FR 50523 (November 1, 2017).

[12] For monthly pipeline entries, see *https://www.cbp.gov/trade/entry-summary/pipeline-monthly-entry-processing/pipeline-line-qa.*

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4513–DR; Docket ID FEMA–2020–0001]

Virgin Islands; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the territory of the U.S. Virgin Islands (FEMA–4513–DR), dated April 2, 2020, and related determinations.

DATES: This amendment was issued July 6, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the territory of the U.S. Virgin Islands is hereby amended to include Individual Assistance limited to the Crisis Counseling Program for those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of April 2, 2020.

Individual Assistance limited to the Crisis Counseling Program for all areas in the territory of the U.S. Virgin Islands (already designated for emergency protective measures [Category B] not authorized under other Federal statutes, including direct Federal assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora

Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–16442 Filed 7–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2020–0015; OMB No. 1660–0110]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; FEMA Preparedness Grants: Nonprofit Security Grant Program

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before August 28, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Information Management Division, 500 C Street SW, Washington, DC 20472, email address *FEMA-Information-collections-management@fema.dhs.gov* or Samrawit Aragie, Program Analyst, FEMA Grant Programs Directorate, Preparedness Grants Program, 202–786–9846 *Samrawit.aragie@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection previously published in the **Federal Register** on May 15, 2020 at 85 FR 29471 with a 60 day public comment period. No comments were received. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: FEMA Preparedness Grants: Nonprofit Security Grant Program (NSGP).

Type of information collection: Revision of a currently approved information collection.

OMB Number: 1660–0110.

Form Titles and Numbers: FEMA Form 089–24 NSGP Prioritization of Investment Justifications; FEMA Form 089–25 NSGP Investment Justification.

Abstract: The Nonprofit Security Grant Program provides funding support for security related enhancements to nonprofit organizations that are at high risk of a terrorist attack. The program seeks to integrate the preparedness activities of nonprofit organizations that are at high risk of a terrorist attack with broader state and local preparedness efforts.

Affected Public: State, and not-for-profit institutions.

Estimated Number of Respondents: 2,086.

Estimated Number of Responses: 2,086.

Estimated Total Annual Burden Hours: 8,960.

Estimated Total Annual Respondent Cost: $338,766.

Estimated Respondents' Operation and Maintenance Costs: $0.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $339,751.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (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.

Maile Arthur,

Acting Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2020–16399 Filed 7–28–20; 8:45 am]

BILLING CODE 9111–46–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2020–0027]

Homeland Security Advisory Council; Meeting

AGENCY: Office of Partnership and Engagement OPE), Department of Homeland Security (DHS).

ACTION: Notice of partially closed Federal advisory committee meeting.

SUMMARY: The Homeland Security Advisory Council (HSAC or Council) will meet in person on Tuesday, August 18, 2020. The meeting will be partially closed to the public and have both an open session and a closed session. Due to the National Emergency concerning the Novel Coronavirus Disease (COVID–19) pandemic members of the public will join the public session by teleconference.

DATES: The meeting will take place from 9:15 a.m. to 3:15 p.m. EDT on Tuesday, August 18, 2020. The meeting will be closed to the public from 9:10 a.m. to 1:40 p.m. EDT. The meeting will be open to the public from 1:45 p.m. to 3:15 p.m. EDT. Please note the meeting may end early if the Council has completed its business. If the times change due to the current National Emergency concerning the COVID–19 pandemic, those members of the public who have signed up for this notice will receive the new time schedule as soon as it becomes available.

ADDRESSES: The meeting will be held in the Town Hall at the Transportation Security Administration (TSA), 601 S

12th Street (East Building), in Arlington, VA 20598. Members of the public interested in participating may do so by following the process outlined below (see ''Public Participation''). Written public comments prior to the meeting must be received by 5:00 p.m. EDT on Friday, August 14, 2020, and must be identified by Docket No. DHS–2020–0027. Written public comments after the meeting must be identified by Docket No. DHS–2020–0027 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: HSAC@hq.dhs.gov.* Include Docket No. DHS–2020–0027 in the subject line of the message.
- *Fax:* (202) 282–9207. Include Mike Miron and the Docket No. DHS–2020–0027 in the subject line of the message.
- *Mail:* Mike Miron, Acting Executive Director of Homeland Security Advisory Council, Office of Partnership and Engagement, Mailstop 0385, Department of Homeland Security, 2707 Martin Luther King Jr. Ave. SE, Washington, DC 20528.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and ''DHS–2020–0027,'' the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read comments received by the Council, go to *http://www.regulations.gov,* search ''DHS–2020–0027,'' ''Open Docket Folder'' and provide your comments.

FOR FURTHER INFORMATION CONTACT: Mike Miron at *HSAC@hq.dhs.gov* or at (202) 447–3135.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under Section 10(a) of the Federal Advisory Committee Act (FACA), Public Law 92–463 (5 U.S.C. Appendix), which requires each FACA committee meeting to be open to the public.

The Council provides organizationally independent, strategic, timely, specific, actionable advice, and recommendations to the Secretary of Homeland Security on matters related to homeland security. The Council is comprised of leaders of local law enforcement, first responders, Federal, State, and Local governments, the private sector, and academia.

The Council will meet in an open session between 1:45 p.m. to 3:15 p.m. EDT. The Council will receive progress reports from the Economic Security, Biometrics, Information and Communication Technology Risk Reduction, and Youth Engagement subcommittees; and senior leadership will announce a new tasking and new Council membership. The HSAC will also review, deliberate, and vote on the final draft report of the Emerging Technology Subcommittee.

Participation: Members of the public will be in listen-only mode. The public may register to participate in this meeting via the following procedures. Each individual must provide his or her full legal name and email address no later than 5:00 p.m. EDT on Friday, August 14, 2020 to Mike Miron of the Council via email to *HSAC@hq.dhs.gov* or via phone at (202) 447–3135. Details on getting access for the conference call will be provided to interested members of the public after the closing of the public registration period and prior to the meeting. For information on services for individuals with disabilities, or to request special assistance, contact Mike Miron at *HSAC@hq.dhs.gov or* (202) 447–3135 as soon as possible.

The Council will meet in a closed session from 9:10 a.m. to 1:40 p.m. EDT to receive sensitive operational information from senior officials on intelligence, border security, transportation security, cybersecurity and infrastructure. *Basis for Partial Closure:* In accordance with Section 10(d) of FACA, the Acting Secretary of Homeland Security has determined this meeting requires partial closure. The disclosure of the information relayed would be detrimental to the public interest for the following reasons:

The Council will receive closed session briefings containing For Official Use Only and Law Enforcement sensitive information from senior officials. The session is closed under 5 U.S.C. 552b(c)(7)(E) because disclosure of that information could reveal investigative techniques and procedures not generally available to the public, allowing terrorists and those with interests against the United States to circumvent the law and thwart the Department's strategic initiatives.

Specifically, there will be material presented during the briefings regarding the latest viable threats against the United States and how DHS and other Federal agencies plan to address those threats. The session is closed pursuant to 5 U.S.C. 552b(c)(9)(B) because disclosure of these techniques and procedures could frustrate the successful implementation of protective measures designed to keep our country safe.

Michael J. Miron,

Acting Executive Director, Homeland Security Advisory Council, Department of Homeland Security.

[FR Doc. 2020–16396 Filed 7–28–20; 8:45 am]

BILLING CODE 9112–FN–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[201A2100DD/AAKC001030/A0A501010.999900 253G; OMB Control Number 1076–0178]

Agency Information Collection Activities; Native American Business Development Institute (NABDI) Funding Solicitations and Reporting

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Indian Affairs (BIA) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before September 28, 2020.

ADDRESSES: Send your comments on this information collection request (ICR) by email to Mr. Jack Stevens, Office of Indian Energy and Economic Development, Office of the Assistant Secretary—Indian Affairs, at: 1849 C Street NW, MS–4152 MIB, Washington, DC 20240; or by email to *Jack.Stevens@bia.gov.* Please reference OMB Control Number 1076–0178 in the subject line of your comments. If you have comments but are unable to email them, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Jack Stevens by email at *Jack.Stevens@bia.gov,* or by telephone at (202) 208–6764.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information

collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the BIA; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the BIA enhance the quality, utility, and clarity of the information to be collected; and (5) how might the BIA minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other 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 Division of Economic Development (DED), within the Office of Indian Energy and Economic Development (IEED), established the Native American Business Development Institute (NABDI) to provide technical assistance funding to federally recognized American Indian Tribes seeking to retain universities and colleges, private consulting firms, non-academic/non-profit entities, or others to prepare feasibility studies of potential economic development opportunities. These studies will empower American Indian Tribes and Tribal businesses to make informed decisions regarding their economic futures. Studies may concern the viability of an economic development project or business or the practicality of a technology a Tribe may choose to pursue. The DED will specifically exclude from consideration proposals for research and development projects; requests for funding of salaries for Tribal government personnel; funding to pay legal fees; funding for the purchase or lease of structures, machinery, hardware or other capital items; and funding related to mineral, energy, or broadband development, as these are addressed by other IEED grant programs

This is an annual program whose primary objective is to create jobs and foster economic activity within Tribal communities. The DED will administer the program within IEED; and studies as described herein will be sole discretionary projects DED will consider or fund absent a competitive bidding process. When funding is available, DED will solicit proposals for studies. To receive these funds, Tribes may, if eligible, obtain adjustments to their funding from the Office of Self-Governance. *See* 25 U.S.C. 450 *et seq.*

Interested applicants must submit a Tribal resolution requesting funding, a statement of work describing the project for which the study is requested, the identity of the academic institution, consultants, or other entity the applicant wishes to retain (if known) and a budget indicating the funding amount requested and how it will be spent. The DED expressly retains the authority to reduce or otherwise modify proposed budgets and funding amounts.

Applications for funding will be juried and evaluated primarily on the basis of a proposed project's potential to generate jobs and economic activity in a Tribal community.

Title of Collection: Native American Business Development Institute (NABDI) Funding Solicitations and Reporting.

OMB Control Number: 1076–0178.

Form Number: None.

Type of Review: Extension without change of currently approved collection.

Respondents/Affected Public: Indian Tribes with trust or restricted land.

Total Estimated Number of Annual Respondents: 20 applicants per year; 20 project participants each year, on average.

Total Estimated Number of Annual Responses: 40.

Estimated Completion Time per Response: 50 hours per application; 1.5 hours per progress report.

Total Estimated Number of Annual Burden Hours: 1,030 hours (1,000 for applications and 30 for final reports).

Respondent's Obligation: Response is required to obtain a benefit.

Frequency of Collection: Once per year for applications and final report.

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.*).

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2020–16404 Filed 7–28–20; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[DOI–BLM–NV–W010–2020–0012–EIS; LLNVW00000.L51100000.GN0000. LVEMF1907180.19X .MO#4500145138]

Notice of Availability of the Draft Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) Humboldt River Field Office, Winnemucca, Nevada, as the lead agency, has prepared a Draft Environmental Impact Statement (EIS) to analyze the potential impacts of approving the Lithium Nevada Corp. (LNC), Thacker Pass Project Proposed Plans of Operations and Reclamation Plan Permit Applications (Project) in Humboldt County, Nevada. In accordance with the Bald and Golden Eagle Protection Act (Eagle Act), the Fish and Wildlife Service (FWS) is a cooperating agency with the BLM on the development of this Draft EIS to analyze the potential impacts of approving LNC's request for an incidental take permit for golden eagles. The FWS will evaluate LNC's Eagle Conservation Plan (ECP), which describes their request for incidental take of eagles and a 5-year incidental take permit for golden eagles under the Eagle Act. This notice announces the beginning of the public comment period to solicit public comments on the Draft EIS.

DATES: To ensure comments will be considered, BLM must receive written comments on the Draft EIS no later than 45 days after the Environmental Protection Agency publishes its notice of availability of the Thacker Pass Lithium Mine Project Draft Environmental Impact Statement DOI–BLM–NV–W010–2020–0012–EIS in the **Federal Register**, and will coordinate with the FWS on any comments received regarding impacts to golden eagles, and the Eagle Act permitting process. The BLM will announce the dates and locations of any future meetings or hearings and any other public involvement activities at least 15 days in advance through local media, newspapers and the BLM website at: *https://www.blm.gov/office/winnemucca-district-office.*

ADDRESSES: You may submit comments related to the Project by any of the following methods:

- *Website: https://bit.ly/2Npgf9l.*
- *Email: blm_nv_wdo_thacker_pass@blm.gov,* include ''Thacker Pass Project EIS Comments'' in the subject line.
- *Fax:* (775) 623–1740, please mark ''Attn: Thacker Pass Project EIS Comments''.
- *Mail:* Bureau of Land Management, Attn: Thacker Pass Project EIS Comments, 5100 E Winnemucca Blvd., Winnemucca, NV 89445.

FOR FURTHER INFORMATION CONTACT: For questions about the proposed Project, contact Mr. Ken Loda, telephone: (775) 623–1500, address: 5100 E Winnemucca Blvd., Winnemucca, NV 89445. Contact Mr. Loda to have your name added to our mailing list. For questions concerning the Eagle Act permitting process, contact Mr. Thomas Leeman at (916) 978–6189. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The applicant LNC proposes to construct, operate, reclaim, and eventually close an open pit lithium mine, processing operation, and continued exploration activities on public lands in northern Humboldt County, Nevada. LNC currently has two approved Plans of Operations (PoOs), one for exploration and one for a specialty clay mine, approved within the area proposed for the new lithium mine. There are 75 acres of exploration disturbance approved under LNC's existing exploration PoO, and 140 acres of existing disturbance approved under their clay mine PoO. LNC has submitted two new PoOs to develop the Project and to provide a description of the proposed lithium mining, processing, and exploration operations. Each of these PoOs include a reclamation plan for the activities identified under the respective PoO. The operations proposed under the two new PoOs would involve a project area of about 18,000 acres, with an ultimate disturbance footprint of approximately 5,700 acres. The proposed lithium mine PoO boundary overlaps the existing PoO boundaries.

LNC proposes to develop the Project in two phases over the estimated 41-year mine life. Pending LNC receiving the required authorizations and permits for Phase 1 of the Project, pre-stripping would commence in early 2021 and construction in the first quarter of 2021, with mining production and ore processing estimated to commence in late 2022. LNC estimates that it would complete mining, processing and concurrent reclamation activities in 2061, after which, reclamation, site closure activities, and post-closure monitoring would occur for a minimum of five years.

The proposed activities and facilities associated with the Project include development of an open pit mine; construction and operation of lithium processing and production facilities, mine facilities to support mining operations, two waste rock storage facilities, a run-of-mine stockpile, a clay tailings filter stack, water supply facilities, two power transmission lines and substations, and various ancillary facilities. Pit dewatering is not expected to be required as part of the Project until 2055, and concurrent backfill of the open pit would occur after sufficient volume has been excavated to initiate direct placement of waste rock. Continued exploration would be conducted under both PoOs. Upon further review the BLM has determined than an amendment to the Winnemucca District Resource Management Plan is not necessary.

In addition, the Project would affect golden eagle nests and territories by planned blasting within a two-mile radius of golden eagle nests; therefore, LNC has requested authorization from the FWS to disturb eagle nests and a 5-year incidental take permit for golden eagles under the Eagle Act. LNC's Eagle Conservation Plan is the foundation of the permit application and contains commitments to avoid, minimize, and mitigate adverse effects on golden eagles resulting from the implementation of the Project. Issuance of an eagle take permit must comply with the Eagle Act and all related regulatory requirements (50 CFR 22.26).

The purpose of this comment period is for the public to comment on the Draft EIS. The Draft EIS, through scoping, has identified and analyzed impacts to the following resources: Air and atmospheric resources; cultural resources; noxious weeds, invasive species, and nonnative species; migratory birds; golden eagles; Native American religious concerns; wastes and materials (hazardous and solid); water quality (surface and ground); geology, minerals and energy; lands and realty; paleontology; rangeland management; recreation; social values and economics; soils; special status species (plants and wildlife); transportation and access; vegetation; visual resources; and wildlife. The Draft EIS describes and analyzes the proposed Project's direct, indirect, and cumulative impacts on all affected resources. In addition to the Proposed Action, Alternative A, the following alternatives are also analyzed in the document: Alternative B, which is a partial backfilling of the pit that would result in a small wet area; Alternative C which does not backfill the pit and would result in three small, and probably seasonal, pit lakes; and the No Action Alternative. Alternatives A, B and C request an eagle take permit for loss of productivity of three golden eagle breeding pairs. Additionally, Alternative C would require nest site enhancement as compensatory mitigation under the Bald and Golden Eagle Protection Act.

The BLM has consulted and continues to consult with Indian tribes on a government-to-government basis in accordance with Executive Order 13175 and other policies. Tribal concerns, including impacts to Indian trust assets and potential impacts to cultural resources have been analyzed in the Draft EIS. Federal, State, and local agencies, along with tribes and other stakeholders that may be interested in or affected by the proposed Project that the BLM and FWS are evaluating, are invited to participate in the comment process.

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 may request in your comment that your personal identifying information be withheld from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1501.7.

Ester McCullough,

Winnemucca District Manager.

[FR Doc. 2020–16448 Filed 7–28–20; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–BSD–FEES–NPS0030498; PX.XBSAD 0113.00.1 (200); OMB Control Number 1024–0252]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; the Interagency Access Pass and Senior Pass Application Processes

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before August 28, 2020.

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 Phadrea Ponds, NPS Information Collection Clearance Officer, 1201 Oakridge Drive, Fort Collins, CO 80525; or by email at *phadrea_ponds@nps.gov.* Please reference OMB Control Number 1024–0252 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR contact Peggi Brooks, Interagency Pass Program Manager, National Park Service by email at *peggi_brooks@nps.gov;* or by telephone at 202–513–7132. Please reference OMB Control Number 1024–0252 in the subject line of your comments. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance. 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 March 12, 2020 (85 FR 14504). No public comments were received in response to this notice.

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 NPS, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of 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 NPS minimize the burden of this collection 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: Authorized by the Federal Lands Recreation Enhancement Act (FLREA; 16 U.S.C. 6801–6814), the America the Beautiful—National Parks and Federal Recreation Lands Pass Program provides recreation opportunities on public lands managed by four Department of the Interior agencies: The National Park Service, U.S. Fish and Wildlife Service, Bureau of Land Management, and the Bureau of Reclamation in addition to the Department of Agriculture's U.S. Forest Service and the U.S. Army Corps of Engineers. This program manages the application process and distribution of passes to provide visitors an affordable and convenient way to access Federal recreation lands. The pass program's proceeds are used to improve and enhance visitor recreation services.

NPS Form 10–596, ''Interagency Access Pass'' is a free, lifetime pass issued to citizens or residents who are domiciled in the United States, regardless of age, who have a medical determination and documentation of permanent disability. Ordering an Access Pass requires a complete application, proof of residency, documentation that proves permanent disability, payment (Lifetime Senior Pass $80 or Annual Senior Pass $20) and the $10 processing fee. Passes can be obtained in person from a participating Federal recreation site or office, through the mail, or on-line via the U.S. Geological Survey (USGS) store at *https://store.usgs.gov/access-pass.*

If a person arrives at a recreation site and claims eligibility for the Interagency Access Pass, but cannot produce any documentation, that person must read, sign, and date NPS Form 10–597, ''Statement of Disability'' in the presence of the agency officer issuing the Interagency Access Pass. If the applicant cannot read and/or sign the form, someone else may read, date, and sign the statement on his/her behalf in the applicant's presence and in the presence of the agency officer issuing the Interagency Access Pass.

NPS Form 10–595, ''Interagency Senior Pass'' is a pass issued to U.S. citizens or permanent residents who are 62 years or older. Senior Passes may be issued on a lifetime or annual basis. Both types of the Senior Pass can be purchased at any federal recreation site, including national parks, that charges an entrance or standard amenity (day-use) fee; online or through the mail from USGS.

Agency websites provide information on the passes and acceptable documentation. All documentation submitted in person or through the mail is returned to the applicant after the form is processed.

Title of Collection: The Interagency Access Pass and Senior Pass Application Processes.

OMB Control Number: 1024–0252.

Form Number: NPS Forms 10–595, 10–596, and 10–597.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Individuals, organizations, businesses, and State, local, or tribal governments.

Total Estimated Number of Annual Respondents: 212,000.

Total Estimated Number of Annual Responses: 212,000.

Estimated Completion Time per Response: Varies from 5 minutes to 10 minutes, depending on activity.

Total Estimated Number of Annual Burden Hours: 22,667.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: $666,000.

An agency may not conduct, or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2020–16435 Filed 7–28–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRSS–NPS0028497; PPWONRADD3, PPMRSNR1Y.NM0000, 199P103601 (200); OMB Control Number 1024–0236]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Research Permit and Reporting System Applications and Reports

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, we, the National Park Service (NPS) are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before August 28, 2020.

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 Phadrea Ponds, NPS Information Collection Clearance Officer, 1201 Oakridge Drive, Fort Collins, CO 80525; or by email at *phadrea_ponds@nps.gov.* Please reference OMB Control Number 1024–0236 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR by mail contact Bill Commins, Natural Resource Stewardship and Science by email at *bill_commins@nps.gov;* or by telephone at 202–513–7166. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the 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 March 18, 2020 (85 FR 15495). We received one response to that notice from the State of Alaska on May 18, 2020. The following comments were received from the State of Alaska requesting changes to the application form:

Comment #1

. . . we request the following question be added to the application, under the section ''Study Schedule.'' • *Is your schedule time sensitive due to biological, weather, or other circumstances beyond your control?*

Comment #2

To increase the utility and clarity of this application (as requested, we request it include a separate box (in item 3) under the section ''*Does your study propose to involve any of the following?*'' • *Alaska Park Units, subject to ANILCA.*

NPS Response

We examined the requests in the context that RPRS is a national system that applies equally to all parks that receive applications for Scientific Research and Collecting Permits. With respect to the first comment, the NPS recognizes that many parks, whether in Alaska, the conterminous states, the Caribbean, or Hawaii and the Pacific Islands, are subject to biological, weather, or other circumstances beyond the control of incoming field teams. We conclude that all parks issuing Scientific Research and Collecting Permits, including the parks in Alaska, are acutely aware of factors that can affect field schedules and as a consequence maintain appropriate flexibilities to work with permittees to modify field schedules as necessary. Because of this awareness, we conclude that park research coordinators do not require redundant notice, therefore we rejected this recommendation.

With respect to the second comment, there is already a section in the application titled: ''*Does your study propose to involve any of the following?* (check all that apply)'' that currently has a check box regarding ''wilderness''. We concluded that adding a second check box specifying ''wilderness in Alaska'' for a permit for studies in Alaska would be unnecessary and redundant, therefore we rejected this recommendation.

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 NPS, 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 NPS 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: NPS policy requires that research studies and specimen collection conducted by researchers, other than NPS employees on official duty, require an NPS scientific research and collecting permit. The permitting process adheres to regulations codified in 36 CFR 2.1 which prohibit the disturbing, removing, or possessing of natural, cultural, and archeological resources. Additionally, regulations codified in 36 CFR 2.5 govern the collection of specimens in parks for the purpose of research, baseline inventories, monitoring, impact analysis, group study, or museum display.

As required by these regulations, a permitting system is managed for scientific research and collecting. NPS forms 10–741a, ''Application for a Scientific Research and Collecting Permit'' and 10–741b, ''Application for a Science Education Permit,'' are used to collect information from persons seeking a permit to conduct natural or social science research and collection activities in individual units of the National Park System. Individuals who receive a permit must report annually on the activities conducted under the permit using form 10–226, ''Investigator's Annual Report.''

The information in this collection is used to manage the use and preservation of park resources, and to report on the status of permitted research and collecting activities. We encourage respondents to use RPRS to complete and submit applications and reports. Additional information about existing applications, reporting forms, guidance and explanatory material can be found on the RPRS website (*https://irma.nps.gov/RPRS/*).

With this renewal we are requesting clearance for the use of a new form, the ''Permittee Field Check-In/Field Check-Out Report.'' Information requested will give parks real time knowledge of what activities are taking place and where, ensuring field work conducted conforms with the permitted activity. For form users on the RPRS, the majority of the new form will be prepopulated using responses from the permit application.

Title of Collection: Research Permit and Reporting System Applications and Reports, 36 CFR 2.1 and 2.5.

OMB Control Number: 1024–0236.

Form Number: NPS Forms 10–226, 10–741a, and 10–741b.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Individuals; businesses; academic and research institutions; and Federal, State, local, and tribal governments.

Total Estimated Number of Annual Respondents: 8,590.

Total Estimated Number of Annual Responses: 8,590.

Estimated Completion Time per Response: Varies from 15 minutes to 83 minutes, depending on activity.

Total Estimated Number of Annual Burden Hours: 5,684.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion for applications; annually for reports.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct, or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2020–16365 Filed 7–28–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 201S180110; S2D2S SS08011000 SX064A000 20XS501520; OMB Control Number 1029–0091]

Agency Information Collection Activities; Requirements for Surface Coal Mining and Reclamation Operations on Indian Lands

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 (PRA, 44 U.S.C. 3501 *et seq.*), 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 August 28, 2020.

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 1029–0091 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 PRA 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 May 7, 2020 (85 FR 27242). 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: Surface coal mining permit applicants who conduct or propose to conduct surface coal mining and reclamation operations on Indian lands must comply with the requirements of 30 CFR 750 pursuant to Section 710 of SMCRA.

Title of Collection: Requirements for Surface Coal Mining and Reclamation Operations on Indian Lands.

OMB Control Number: 1029–0091.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Applicants for coal mining permits on Indian lands.

Total Estimated Number of Annual Respondents: 2.

Total Estimated Number of Annual Responses: 30.

Estimated Completion Time per Response: Varies from 143 to 731 hours, depending in activity.

Total Estimated Number of Annual Burden Hours: 5,468.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Once.

Total Estimated Annual Nonhour Burden Cost: $34,000.

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. 2020–16391 Filed 7–28–20; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0002]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Application for Restoration of Firearms Privileges—ATF Form 3210.1

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), 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 August 28, 2020.

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:* Extension without change of a currently approved collection.

(2) *The Title of the Form/Collection:* Application for Restoration of Firearms Privileges.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 3210.1.

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: None.

Abstract: The information requested on the Application for Restoration of Firearms Privileges—ATF Form 3210.1, fulfills the requirements of 18 U.S.C. Chapter 44. Specifically, individuals prohibited from purchasing, possessing, receiving, or transporting firearms, are permitted to apply for the restoration of their firearms privileges, using ATF Form 3210.1. Currently, only corporations may apply for relief, since Congress has not appropriated funds for individuals who are prohibited.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 10 respondents will utilize the form annually, and it will take each respondent approximately 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 five (5) hours, which is equal to 10 (# of respondents) * 1 (# of responses per respondent) * .5 (30 minutes or the time to complete each response).

(7) *An Explanation of the Change in Estimates:* Due to a congressional restriction, use of this IC is currently limited to corporations and not individuals. As such, the total respondents has reduced by 240, since the last renewal in 2017. Although postage costs increased from .49 per respondent during the 2017 to $0.55 currently, the total public cost burden reduced by $117.50.

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, 3E.405A, Washington, DC 20530.

Dated: July 23, 2020.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020–16351 Filed 7–28–20; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0076]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Application for Restoration of Explosives Privileges—ATF Form 5400.29

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), 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 August 28, 2020.

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 for Restoration of Explosives Privileges.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 5400.29.

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: Individuals or households.

Other: Business or other for-profit.

Abstract: Persons who wish to ship, transport, receive, or possess explosive materials, but are prohibited from doing so, must complete the Application for Restoration of Explosives Privileges—ATF Form 5400.29. The completed form must be submitted to ATF, to determine if the applicant is likely to act in a manner that endangers public safety, and that granting relief is not contrary to the public interest.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 300 respondents will utilize the form annually, and it will take each respondent approximately 30 minutes to complete the form.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 150 hours, which is equal to 300 (# of respondents) * 1 (# of responses per respondents) * .5 (30 minutes or the total time to complete each response).

(7) *An Explanation of the Change in Estimates:* The adjustment to this IC include an increase in the public burden cost to $9,765, which is due to inclusion of the cost to conduct ATF in-person interviews with both the respondent's supervisor and a coworker, as well as mailing costs.

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, 3E.405A, Washington, DC 20530.

Dated: July 23, 2020.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020–16350 Filed 7–28–20; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Salvatore Cavaliere, D.O.; Decision and Order

On April 2, 2018, the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Salvatore Cavaliere, D.O. (hereinafter, Respondent). OSC, at 1. The OSC proposed the revocation of Respondent's Certificate of Registration No. FC2341876 pursuant to 21 U.S.C. 824(a)(4) ''because [he had] committed acts which render [his] registration inconsistent with the public interest . . . .'' *Id.* (citing 21 U.S.C. 823(f) and 824(a)).

I. Procedural History

Specifically, the OSC alleged that Respondent sold to an acquaintance, approximately 32,000 dosage units of Lortab [1] and approximately 16,000 dosage units of Norco [2] outside of the usual course of professional practice in violation of 21 CFR 1306.04(a). *Id.* at 2–3. The OSC also alleged that Respondent failed to maintain records required by both federal and state law. *Id.* at 3–4. Specifically, it alleged that Respondent failed to maintain and provide a dispensing log in violation of 21 CFR 1304.03(b) and 1304.21(a), Mich. Comp. Laws Ann. §§ 333.7303a and 333.17745 (West 2020),[3] and Mich. Admin. Code r.

[1] Lortab is hydrocodone bitartrate/acetaminophen 7.5/500mg—which at the time was a Schedule III controlled substance. *Id.* at 2.

[2] Norco is hydrocodone bitartrate/acetaminophen 7.5/325mg—a Schedule III controlled substance until October 2014, and a Schedule II controlled substance since October 2014. *Id.* at 2. Hereinafter, ''hydrocodone bitartrate/acetaminophen'' will be used to refer to Lortab and Norco collectively.

[3] Throughout this Decision, I have cited to the Michigan Compiled Laws Annotated current through P.A. 2020, No. 129, of the 2020 Regular Session, 100th Legislature. Although I have cited to a contemporary compilation, the substantive portions of the Michigan Compiled Laws that I cite in this Decision were in effect at all times relevant to this case. *See* Mich. Comp. Laws Ann. (West, current through P.A. 2010, No. 383 (End) of the

Continued

338.3153 (2020),[4] or copies of his inventories of controlled substances in violation of 21 CFR 1304.11(c) and Mich. Admin. Code r. §§ 338.3151 and 338.3152.[5] *Id.* Finally, the OSC alleged that Respondent issued prescriptions outside of the usual course of professional practice and beneath the standard of care for the State of Michigan in violation of 21 CFR 1306.04(a), and he failed to document adequate patient files for eight individual patients in violation of Mich. Comp. Laws Ann. §§ 333.7303 and 333.16213. *Id.* at 4–5.

The OSC notified Registrant of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 6 (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. OSC, at 6 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated May 1, 2018, Respondent timely submitted a designation of representative, which stated, ''My client desires to waive any hearing in this cause.'' [6] Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter, RFAAX) B, at 1. Simultaneously, Respondent submitted a proposed Corrective Action Plan.[7] *Id.* at 3–8. On May 15, 2018, a former Assistant Administrator of the Diversion Control Division rejected Respondent's proposed Corrective Action Plan and ''den[ied] the request to discontinue or defer administrative proceedings.'' RFAAX C.

On March 22, 2019, the Government forwarded its RFAA, along with the evidentiary record in this matter, to my office. Attached to the RFAA were 383 pages of exhibits including, but not limited to, declarations from a DEA Diversion Investigator and a DEA Special Agent, 62 pages of prescriptions issued by Respondent, 33 pages of patient records, and 216 pages of text messages from Respondent's cell phone. RFAAX A–G. The RFAA asserted that ''Respondent has waived his right to a hearing in this matter and did not file a written statement of position in lieu of a hearing request.'' RFAA, at 1. Despite Respondent's waiver the Government certified that the RFAA and all of the exhibits thereto were served on Respondent's representative. RFAA, at 33.

Having considered the record in its entirety, I find that the record establishes, by substantial evidence, that Respondent committed acts rendering his continued registration inconsistent with the public interest. I further find that revocation is the appropriate sanction. Based on the representations of the Government in its RFAA, I make the following findings of fact.

II. Findings of Fact

A. Respondent's DEA Registration

Respondent is registered with DEA as a practitioner in schedules II through V under DEA Certificate of Registration No. FC2341876, at 525 East Big Beaver Road, Suite #100, Troy, MI 48083. RFAAX D (Controlled Substance Registration Certificate). This registration expired on August 31, 2019.[8] *Id.*

B. Overview of the Government's Evidence Supporting the Allegations

As discussed above, the Government alleged three factual bases for the revocation of Respondent's registration pursuant to 21 U.S.C. 824(a)(4) and 823(f). OSC, at 1. First, the Government alleged that Respondent dispensed and sold controlled substances (specifically hydrocodone bitartrate/acetaminophen) to an acquaintance outside of the ordinary course of professional practice. *Id.* at 2–3. As evidence in support of this allegation, the Government presented DEA records from the Automation of Reports and Consolidated Orders System (hereinafter, ARCOS) and records received from McKesson Corporation pursuant to a subpoena showing Respondent's purchases of hydrocodone bitartrate/acetaminophen. RFAAX E–1 (Respondent's Purchase History from ARCOS), and E (Declaration of DI), at 1–2. The Government presented records of prescriptions for controlled substances that Respondent issued to individual B.S., which were received pursuant to a subpoena on CVS Pharmacy. RFAAX E–3 (Copies of Prescriptions Issued by Respondent to B.S.), and E, at 2–3. The Government presented copies of text messages between individual B.S. and Respondent that were received from Respondent's cell phone pursuant to a search warrant on July 13, 2016. RFAAX E–4 (Text Messages Between respondent and B.S.), and E, at 3. And finally, the Government presented the affidavit of a DEA Diversion Investigator (hereinafter, DI), which summarized her investigation, including the statements made by B.S. during an interview. RFAAX E.

Second, the Government alleged that Respondent was unable to provide to DEA various records that Respondent was required by law to maintain. *Id.* at 3–4. As evidence in support of this allegation, the Government presented the affidavit of DI regarding the results of a search warrant executed at Respondent's registered address on July 13, 2016. RFAAX E, at 3.

And third, the Government alleged that Respondent issued prescriptions outside of the usual course of professional practice and beneath the standard of care in the State of Michigan, and that he failed to maintain complete patient files for seven [9] individual patients. *Id.* at 4–5. As evidence in support of this allegation, the Government presented patient records received from Respondent pursuant to an administrative subpoena issued by a DEA Special Agent (hereinafter, SA) that was served on October 30, 2017, and answered on November 16, 2017. RFAAX F (Declaration of SA), including Exhibits F–1 through F–7 (Patient Files), and F–9 (Letter from Respondent's Representative dated November 15, 2017). The Government presented pharmacy records received by the SA (pursuant to administrative subpoenas) during the course of her investigation. RFAAX F–8 (Copies of Prescriptions Issued by Respondent), and F, at 2. And finally, the Government presented evidence from its expert witness, R. Andrew Chambers, M.D., regarding the applicable standard of care. RFAAX G (Declaration of R. Andrew Chambers,

2010 Regular Session of the Michigan Legislature, 95th Legislature).

[4] Throughout this Decision, I have cited to the Michigan Administrative Code current through June 15, 2020. Although I have cited to the contemporary version, the substantive portions of the Michigan Administrative Code that I cite in this Decision were in effect at all times relevant to this case. *See* Mich. Admin Code r. §§ 338.3151–3153 (2002).

[5] The OSC contained a third record keeping allegation, but the Government appears to have abandoned the third allegation and did not include any evidence in support of the allegation or otherwise brief the issue in the RFAA; therefore, I am not including it herein. *Compare* OSC, at 3–4, *with,* RFAA, at 9, 30–31.

[6] As the Respondent filed a designation of representative and submitted a Corrective Action Plan as permitted by the OSC, I find that the Government's service of the OSC was adequate.

[7] Respondent's proposed Corrective Action Plan would, among other things, have Respondent follow the various laws he was alleged to have violated, meet quarterly with a ''physician monitor,'' complete eight hours total of continuing medical education in recordkeeping and substance abuse addition, and surrender his DEA Certificate of Registration for six months. RFAAX B.

[8] The fact that a registrant allows his registration to expire during the pendency of an OSC does not impact my jurisdiction or prerogative under the Controlled Substances Act (hereinafter, CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.,* 84 FR 68,474 (2019).

[9] In the RFAA, the Government abandoned the allegations as to one patient, C.C. *Compare,* OSC, at 4, *with* RFAA, at 10–14.

M.D.), and G–1 (Curriculum Vitae of R. Andrew Chambers, M.D.).

C. Applicable Standard of Care in the State of Michigan

The Government retained Dr. Chambers to review medical files obtained during the investigation for seven patients, and to evaluate the medical files for compliance with the standard of care and usual course of the professional practice in Michigan. Dr. Chambers is a practicing, board-certified addiction psychiatrist. RFAAX G, at 1; and G–1, at 1–2. He is also an Associate Professor of Psychiatry at the Indiana University School of Medicine, Department of Psychiatry, IU Neuroscience Center and the head of the Addiction Psychiatry Training Program ''where [h]e train[s] psychiatrists and physicians on the diagnosis and treatment of mental illness and drug addiction.'' RFAAX G, at 1. Although Dr. Chambers is licensed in Indiana, he has ''reviewed various materials to familiarize [him]self with the standard of care for the prescribing of controlled substances in Michigan.'' *Id.* at 3. Moreover, DEA previously found that ''Dr. Chambers [was] qualified to provide an expert opinion on the standards of professional practice for prescribing controlled substances under the Michigan Board's Guidelines and Michigan law,'' among other things. *Bernard Wilberforce Shelton, M.D.,* 83 FR 14,028, 14,036 (2018). I find that Dr. Chambers is an expert in the standards of professional practice for prescribing controlled substances in Michigan and I credit his uncontroverted report.

Dr. Chambers credibly declared that, in Michigan, ''any controlled substance must be prescribed for a legitimate or professionally recognized therapeutic purpose.'' RFAAX G, at 4. To properly determine whether a prescription has a legitimate or professionally recognized therapeutic purpose, ''a practitioner must take a complete medical history of the patient and conduct an adequate examination to determine if there is a legitimate medical basis for so prescribing.'' *Id.* Pursuant to § 333.7303a of the Michigan Compiled Laws, before prescribing or dispensing a controlled substance to a patient, a licensed provider must ''ask the patient about other controlled substances the patient may be using. The prescriber shall record the patient's response in the patient's medical or clinical record.'' Mich. Comp. Laws Ann. § 333.7303a (West 2020); *see also* RFAAX G, at 4.

Dr. Chambers stated that when evaluating the use of controlled substance for pain control specifically, ''a complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of pain on physical and psychological function, and history of substance abuse.'' RFAAX G, at 4. Dr. Chambers attested based on his knowledge and experience ''that taking a complete medical history and documenting the patient's complaint, medical history, and history of substance abuse is required to meet the standard of care for the prescribing of any controlled substance, not just those prescriptions which relate to pain control.'' RFAAX G, at 5.

Regarding recordkeeping, under Michigan law, a physician ''shall keep and maintain a record for each patient for whom he or she has provided medical services, including a full and complete record of tests and examinations performed, observations made, and treatments provided.'' Mich. Comp. Laws Ann. § 333.16213(1) (West 2020); *see also* RFAAX G, at 5. This record must be maintained ''for a minimum of 7 years from the date of service to which the record pertains.'' *Id.* Similarly, ''[a] dispensing prescriber shall include in a patient's chart of clinical record a complete record, including prescription drug names, dosages, and quantities, of all prescription drugs dispensed directly by the dispensing prescriber.'' *Id.* (citing, Mich. Comp. Laws Ann. § 333.17745(3) (West 2020)). Dr. Chambers attested based on his knowledge and experience, ''that keeping accurate and complete patient records is required to meet the standard of care for the prescribing of any controlled substance.'' RFAAX G, at 5.

Having read and analyzed all of the record evidence and law, I find that Dr. Chambers' declaration concerning a Michigan physician's standard of care when prescribing controlled substances is supported by substantial evidence—in particular that it is consistent with the explicit text of Michigan law and Michigan Guidelines. As such, I apply the standard of care for the State of Michigan as described by Dr. Chambers and Michigan law.

D. Allegation That Respondent Unlawfully Dispensed/Sold Controlled Substances to B.S.

Having read and analyzed all of the record evidence, I find that the Government has demonstrated by substantial evidence that Respondent unlawfully sold and dispensed controlled substances, namely hydrocodone bitartrate/acetaminophen,[10] to B.S. without a legitimate medical purpose.

DI ''began an investigation into Respondent after receiving information that Respondent was providing an individual with the initials B.S. with entire bottles of hydrocodone bitartrate/acetaminophen products in exchange for cash.'' RFAAX E, at 1. On September 28, 2016, DI participated in an interview of B.S.[11] *Id.* at 4. During that interview, ''B.S. explained that she had received controlled substances and prescription[s] for controlled substances from Respondent without a legitimate medical purpose between approximately late 2001 until August 2015.'' *Id.*

More specifically, B.S. explained that at some point after she met Respondent, she went to dinner with him and ''told Respondent that she took 'Vicodin' and asked whether he knew anyone that would sell her pain medication.'' *Id.* According to B.S., Respondent said that ''he would help [B.S] obtain Vicodin by calling prescriptions into pharmacies for her . . . [and] that he could provide her with whole bottles of controlled substances.'' *Id.* There is no indication in the record that B.S. was a patient of Respondent's, that B.S. visited Respondent at his medical practice, or that Respondent conducted any examination of B.S.[12] *See,* RFAAX E, and E–1—E–4.

[10] Hydrocodone bitartrate/acetaminophen is often marketed under the brand name ''Vicodin,'' but other brand names include ''Norco'' and ''Lortab.'' RFAA, at 3 (citing National Drug Code Directory, *https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm*). Prior to October, 2014, hydrocodone was a Schedule III controlled substance, but since October 6, 2014, it has been a Schedule II controlled substance. RFAA, at 3 (citing 79 FR 49,661 (2014)).

[11] The only evidence in the record reflecting B.S.'s statements comes from DI's affidavit memorializing the September 28, 2016 interview of B.S. (DI participated in the interview). RFAAX E, at 4–5. Even assuming B.S.'s statements are hearsay, I will consider them. ''Provided it is relevant and material, hearsay is admissible in [an] administrative proceeding,'' and may ''under certain circumstances . . . constitute substantial evidence.'' *Mireille Lalanne, M.D.,* 78 FR 47,750, 47,752 (2013) (citing *Bobo* v. *U.S. Dept. of Agric.,* 52 F.3d 1406, 1414 (6th Cir. 1995) (internal citations omitted)). Here, the record reflects that declarant died in April 2017 (RFAAX E, at 5) and is therefore unavailable to provide direct affidavit or testimony; there is no indication B.S.'s statements are biased and are likely against B.S.'s own interest; B.S.'s statements are not contradicted by any of the evidence in the record—in fact B.S.'s statements are strongly corroborated by the relevant evidence in the record. As such, I find that B.S.'s statements as captured by DI's affidavit have demonstrated reliability and credibility as discussed throughout this section and I afford them full weight.

[12] Instead, the record reflects that B.S. would often leave money for Respondent in her mailbox

Continued

DI learned that B.S. and Respondent would communicate by text message. RFAAX E, at 4. ''In the text message[s], B.S. would refer to the Vicodin as 'books' and Valium as 'magazines.' '' *Id.* In the beginning, Respondent would order and deliver two, 500-count bottles of hydrocodone bitartrate/acetaminophen to B.S. at her house for $2,000.[13] RFAAX E, at 4. Later, beginning in either 2013 or 2014, Respondent began to deliver ten, 100-count bottles of hydrocodone bitartrate/acetaminophen for $2,000.[14] *Id.* ''B.S. indicated that she took all of the pills that Respondent sold her—as many as 30 a day . . . .'' *Id.* at 5.

DEA, pursuant to a search warrant and with Respondent's consent, had a forensic technician image Respondent's cell phone. *Id.* at 3. As a result of that process, DI was able to obtain and review the text messages between Respondent and B.S. *Id.* ''[DI] read B.S. various examples of the text messages that were recovered from Respondent's cell phone . . . and B.S. confirmed that they referred to the purchase of controlled substances by B.S. from Respondent.'' *Id.* at 5. I find that the text messages between Respondent and B.S. corroborate the information provided by B.S. during her interview.

Further, the evidence demonstrates that Respondent and B.S. exchanged text messages regarding the purchase of 'books' in close temporal proximity to Respondent placing orders for controlled substances. *See* RFAAX E–4. The below example is illustrative:

Example 1:

- 6/13/2013, 1:35 p.m., from Respondent to B.S.: ''Barb I need to put in the order for books. Do you want me to get you some magazines?'' RFAAX E–4, at 140.
- 6/13/2013, 7:23 p.m., from B.S. to Respondent: ''Hi Sal that would b great. Thank u[.]'' *Id.* at 139.
- 6/19/2013, transaction date for two bottles, for a total of 1,000 dosage units of Hydrocodone Bit.7.5MG/Acetamin tablets is reported by McKesson Corporation for Respondent. RFAAX E–1, at 2.
- 6/22/2013, 6:27 p.m., from B.S. to Respondent: ''Hi Sal how r u? Can u let me know when the books come in? Thank you[.]'' RFAAX E–4, at 135.
- 6/22/2013, 6:30 p.m., from Respondent to B.S.: ''They're in. At funeral home call later[.]'' *Id.* at 134.
- 6/24/2013, 7:16 p.m., from B.S. to Respondent: ''Hi Sal how r u? Can we meet up tomarrow [sic.] because I'm going out of town Wed. morning? Thank you[.]'' *Id.* at 133.
- 6/24/2013, 10:21 p.m., from Respondent to B.S.: ''Ok. How's 9. I have a meeting til [sic.] 8:30 downtown Detroit[.]'' *Id.* at 132.
- 6/24/2013, 10:23 p.m., from B.S. to Respondent: ''That would b great!'' *Id.*
- 6/25/2013, 8:04 a.m., from Respondent to B.S.: ''C u then[.]'' *Id.*

During her interview, B.S. explained, ''On occasion, B.S. would run out of Vicodin between shipments and Respondent would write her a prescription to 'help her out.' '' RFAAX E, at 5. I find that the text messages between Respondent and B.S. and the record as a whole corroborates this statement. For example:

Example 2:

- 12/30/2013, 11:22 a.m., from Respondent to B.S.: ''Barb. I'll be putting in an order for the books Thursday[.] I'll hold off on the magazines and order those next month. I'm trying to stay on top of things in case there are back orders or delays[.]'' RFAAX E–4, at 105.
- 12/30/2013, 7:23 p.m., from B.S. to Respondent: ''Sounds great . . . thank u[.]'' *Id.* at 104.
- 1/9/2014, 8:01 p.m., from B.S. to Respondent: ''Hi Sal how r u? Can u let me know when the books come in? Thank u[.]'' *Id.* at 103.
- 1/13/2014, 3:02 p.m., from Respondent to B.S.: ''Orders have been changed. The books come in bottles of 100 and not 500 as before. So an order will be placed on Friday [1/17/14] for 10 bottles of 100 same cost. I knew there was going to be a glitch. So they should be in next week. Ok?'' *Id.* at 102.
- 1/13/2014, 10:15 p.m., from B.S. to Respondent: ''Hi I just got ur message. I only have a couple left and I'm really starting to worry. Thank u for trying.'' *Id.* at 101.
- 1/18/2014, 12:19 a.m. (in three parts), from B.S. to Respondent: ''Hi Sal sorry to text u so late. I don't have any books left and I feel sooo terrible. I don't know what to do and I'm sorry to bother u with this but can . . . u PLEASE call in a script I am just really getting sick? If u can the number is [redacted] b-day [redacted] CVS. I am so sorry but I don't want to check [into] a treatment center. I'm sorry to bother u.'' *Id.* at 100.
- 1/18/2014, 12:13 p.m., from Respondent to B.S.: ''Done. Ready in 1 hour.'' *Id.*
- 1/18/2014, 1:15 p.m., from B.S. to Respondent: ''Thank u[.]'' *Id.* at 99.
- 1/18/2014, Prescription issued from Respondent to B.S. for Hydrocodone Bitartrate—Acetaminophen, 300 MG–7.5 MG, quantity 50. RFAAX, E–2 (MAPS Report Showing Prescriptions Issued to B.S.). *See also* E–3, at 3.
- 1/23/2014, 11:51 p.m., from B.S. to Respondent: ''Hi Sal please call me when the books come in. Thank you[.]'' RFAAX E–4, at 98.
- 1/24/2014, 5:39 a.m., from Respondent to B.S.: ''I called them yesterday. They didn't call me back. I'm so irate. I told them its been three weeks. I'm calling again today[.]'' *Id.* at 97.
- 1/27/2014, 7:20 p.m., from B.S. to Respondent: ''Hi Sal do u know when the books r coming in?'' *Id.* at 96.
- 1/28/2014, transaction date for ten bottles for a total of 1,000 dosage units of Hydrocodone Bitartrate/Aceta 7 tablets is reported by McKesson Corporation for Respondent. RFAAX E–1, at 2.
- 1/28/2014, 9:00 p.m., from B.S. to Respondent: ''Hi Sal do u think they will b in tommarrow [sic.]?'' RFAAX E–4, at 95.
- 1/28/2014, 10:32 p.m., from Respondent to B.S.: ''I'll call. . . . As I said. I can give you some thurs to hold you by til they come in[.]'' *Id.*
- 1/28/2014, 10:36 p.m., from B.S. to Respondent: ''O.k. Thank u. I have been getting really sick I've been in bed sick so please do that. I can buy them if u want I just REALLY need them.[T]hank u[.]'' *Id.*
- 1/30/2014, 8:38 p.m., from B.S. to Respondent: ''Hi Sal my brother came over because I have the flu. Can u PLEASE put them in the mailbox so he does not see. Please text me. Thank u[.]'' *Id.* at 94.

In addition to being supported by the text messages, B.S.'s statements to DI are supported by other evidence in the record. Specifically, DEA's ARCOS records show ''that Respondent had purchased approximately 48,000 dosage units of hydrocodone/acetaminophen from McKesson Corporation between 2011 and 2015.'' RFAAX E, at 1–2. Additional records show that, ''between September 2012 and June 2014, Respondent purchased 22 100-count bottles of Diazepam [also called Valium] 10mg from McKesson Corporation.'' *Id.* at 2. Respondent's final purchase from

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and Respondent would leave the controlled substances on her porch or at her back door. *See* RFAAX E–4, at 61 (''Hi Sal . . . I left $ in the mailbox. Can u leave on porch I'l[l] bring in latee [sic.].''). *See also id.* at 3, 83, 84, 94, 110, 116, 119, 127, 147, 150, 188, 196, and 198.

[13] I find that the text messages in the record corroborate B.S.'s statement as to the price charged by Respondent. For example:

- ''You just owe 1000 since the other one never came in.'' RFAAX E–4, at 198.
- ''Sorry mags are 100 each[.]'' *Id.* at 173.
- ''I do have an order for 4 books and 6 magazines. Total $4600[.]'' *Id.* at 130.
- ''They sent me 20. So it's two months. $4k[.]'' *Id.* at 84.

[14] Respondent would also order and deliver to B.S. upon request, 100-count bottles of Valium for $100. *Id.* However, the Government did not pursue any action related to Respondent's sale of Valium, so I am not including the Valium in my findings.

McKesson Corporation was on August 12, 2015, which aligns with B.S.'s statement that she ''decided to quit illegally taking controlled substances in August 2015[,] and that she stopped buying controlled substances from Respondent at that point.'' RFAAX E at 5; and E–1, at 3.

In short, I credit B.S.'s statements as reflected in DI's affidavit—B.S.'s statements are not only uncontradicted, but they are fully supported and corroborated by the relevant evidence in the record. Additionally, based on the entire body of evidence before me, I find that between March 2011 and August 2015, Respondent sold and dispensed controlled substances (hydrocodone bitartrate/acetaminophen) to B.S. approximately 45 times (a total of approximately 48,000 dosage units) without any evidence of a valid doctor-patient relationship.[15]

E. Allegation That Respondent Failed To Maintain Controlled Substances Records

Having read and analyzed all of the record evidence, I find that the Government has proven by substantial evidence that Respondent was unable to provide DEA with a dispensing log or inventory. RFAA, at 9. On July 13, 2016, DEA executed a federal search warrant at Respondent's registered address. RFAAX E, at 3. ''During the execution of the search warrant, [DI] requested that Respondent provide [DI] with dispensing records for the controlled substances he had purchased from McKesson Corporation.'' *Id.* Respondent informed DI ''that no dispensing log had ever been kept. . . .'' *Id.* Finally, DI requested that Respondent ''provide [her] with copies of any inventories of controlled substances[, but Respondent] did not provide them.'' *Id.* I find that Respondent did not provide a dispensing log or an inventory to DI.

F. Allegation That Respondent Issued Prescriptions for Controlled Substances Outside the Usual Course of the Professional Practice and in Violation of Michigan Law

The Government submitted a declaration from SA attesting that, ''[o]n October 30, 2017, [SA] served an administrative subpoena . . . on Respondent requesting patients records for . . . individuals who had been prescribed testosterone by Respondent during 2017.'' RFAAX F, at 1. On November 16, 2017, SA received copies of the requested patient records from Respondent along with a letter ''explain[ing] that the provided materials represented 'all the records [Respondent] ha[d] in reference to the patients delineated in attach[ment] to the Subpoena. . . .''' *Id.* at 1 (citing F–9). The issuance of prescriptions to and maintenance of records for seven patients, D.K., F.C., M.A., M.D., S.C., S.D., and S.H., are at issue in this matter. RFAA, at 9–14. Dr. Chambers reviewed the patient files maintained by Respondent for these seven patients and reviewed copies of certain prescriptions for controlled substances issued by Respondent to these patients. RFAAX G, at 6.

1. Patient D.K.

According to the subpoenaed pharmacy records, Respondent issued a prescription to D.K. for ''testosterone cypionate'' [16] on November 6, 2014, with one refill.[17] RFAAX F–8, at 6. The prescription was filled on November 7, 2014, and refilled on January 29, 2015. *Id.* at 7–9. The earliest dated patient record received from Respondent regarding D.K. was dated February 26, 2015.[18] *See* RFAAX F–1. On February 26, 2015, D.K. signed a ''Consent for Hormone Supplementation Therapy,'' and filled out a ''Comprehensive History Evaluation,'' but it was not fully completed. *Id.* at 2–3. For example, ''Reason for today's visit:'' was left blank; none of the yes or no questions, such as ''SOCIAL HISTORY: . . . Recreational Substance: YES/NO,'' were completed; and the ''CURRENT MEDICATIONS/VITAMINS:'' section was also left blank. *Id.* at 2. Respondent's records for D.K. also included ''Progress Notes,'' which begin on February 26, 2015, by documenting the administration of testosterone to D.K. *Id.* at 4, and RFAAX G, at 6.

Dr. Chambers pointed out that the earliest dated document in D.K.'s patient file was dated ''more than three months after Respondent issued Patient D.K. a prescription for a controlled substance.'' *Id.* at 7. Additionally, ''Respondent failed to document the prescription that was issued in November 2014 and failed to maintain any records relating to that prescription or relating to any medical examinations performed or observations made prior to the issuance of that prescription.'' *Id.*

Dr. Chambers, based on his review of the patient file for D.K., opined, and I agree, that Respondent ''failed to document an adequate medical history; failed to document the patient's complaint; failed to document the patient's use of other controlled substances, and failed to properly maintain medical records as required under Michigan law.'' RFAAX G, at 6. Dr. Chambers further concluded, and I agree, that ''the prescription issued by Respondent to Patient D.K. dated November 6, 2014, was issued outside of the standard of care in the state of Michigan and outside the usual course of professional practice.'' *Id.*

2. Patient F.C.

According to the subpoenaed pharmacy records, Respondent issued a prescription to F.C. for ''Cheratussin AC Syrup'' [19] on August 28, 2011, with one refill.[20] RFAAX F–8, at 38. The earliest dated patient record received from Respondent for F.C. was a ''Progress Note,'' dated November 1, 2011, regarding testosterone and progesterone. *See* RFAAX F–2, at 3; RFAAX G at 7. In addition to the ''Progress Notes,'' Respondent's patient file for F.C. contained an undated contact sheet for F.C. and an undated ''Comprehensive History Evaluation'' that was not fully completed. RFAAX F–2, at 1–2. For example, ''Reason for today's visit:'' was left blank; the yes or no question, ''SOCIAL HISTORY: . . . Recreational Substance: YES/NO,'' was not completed; and the ''PAST MEDICAL HISTORY'' and ''FAMILY HISTORY'' sections were left blank. *Id.* at 2.

There is no mention of the Cheratussin AC prescription in the November 1, 2011, ''Progress Note''—in fact, there is no mention of Cheratussin AC anywhere in the patient file, and Respondent issued additional prescriptions to F.C. for Cheratussin dated May 2, 2013, October 3, 2014, and May 24, 2015. RFAAX F–2, at 3; F–8, at 31–37; G at 8.

Dr. Chambers pointed out that ''Respondent failed to document the Cheratussin AC prescriptions that were issued to Patient F.C. between August 2011 and May 2015, and failed to maintain any records relating to those prescription[s] or relating to any medical examinations performed or observations made prior to the issuance of those prescriptions.'' *Id.* He went on to observe that ''Patient F.C.'s patient

[15] This finding is further supported by my finding below that Respondent maintained no records as to the purchases from McKesson Corporation.

[16] Dr. Chambers stated that ''testosterone cypionate'' is a Schedule III controlled substance. RFAAX G, at 6.

[17] There are no records related to the prescription dated November 6, 2014, in the patient file. RFAAX F–1 (Patient File for Patient D.K.).

[18] Respondent's records contained an undated record with D.K.'s general information, such as date of birth and contact information. RFAAX F–1, at 1.

[19] Dr. Chambers stated that ''Cheratussin AC'' is a Schedule V controlled substance. RFAAX G, at 7–8.

[20] There are no records related to the prescription dated August 28, 2011, in the patient file. RFAAX F–2 (Patient File for Patient F.C.).

file does not include any records of any examinations or visits related to the [Cheratussin AC] prescriptions nor does it provide any basis to assess the reason for the issuance of a Cheratussin AC prescription to Patient F.C.'' *Id.* Per Dr. Chambers, ''[w]hile the patient 'progress notes' reference various hormone prescriptions, the Cheratussin AC prescriptions are not documented in the patient file.'' *Id.*

Dr. Chambers, based on his review of the patient file for F.C., opined, and I agree, that ''Respondent failed to document the patient's complaint; failed to document the patient's use of other controlled substances; and failed to properly maintain medical records as required under Michigan law.'' RFAAX G, at 8. Dr. Chambers further concluded, and I agree, that ''four prescriptions issued by respondent to Patient F.C. dated August 28, 2011; May 2, 2013; October 3, 2014; and May 24, 2015, were issued outside of the standard of care in the state of Michigan and outside the usual course of professional practice.'' *Id.*

3. Patient M.A.

According to the subpoenaed pharmacy records, Respondent issued a prescription for ''Vicodin'' [21] to M.A., dated June 6, 2011.[22] RFAAX F–8, at 24–25. The earliest patient record received from Respondent regarding M.A. was a contact sheet, dated December 10, 2014. *See* RFAAX F–3, at 1. The only other records in the patient file are a document titled ''Informed Consent to Perform A Hair Transplant . . .'' signed and dated December 11, 2014, and, according to Dr. Chambers, ''an untitled sheet of paper potentially indicating the administration of testosterone to Patient M.A. on three occasions'' between April 2015 and June 2017. RFAAX F–3, at 2–3, and G, at 9.

Dr. Chambers opined that, ''Respondent's patient file for Patient M.A. does not include *any* medical history; does not include *any* documentation regarding any examinations or tests performed; does not include *any* assessment or diagnosis of Patient M.A.'' *Id.* Dr. Chambers also stated that it is significant that ''the information sheet is dated . . . years after the prescription for controlled substances was issued.'' *Id.*

Dr. Chambers, based on his review of the patient file for M.A., opined, and I agree, that ''Respondent failed to conduct or document an adequate physical exam; failed to document an adequate medical history; failed to document the patient's complaint; failed to document the patient's use of other controlled substances; and failed to properly maintain medical records as required under Michigan law.'' RFAAX G, at 9. Dr. Chambers further concluded, and I agree, that ''the prescription issued by Respondent to Patient M.A. dated June 6, 2011[,] was issued outside of the standard of care in the state of Michigan and outside the usual course of professional practice.'' *Id.* at 10.

4. Patient M.D.

According to the subpoenaed pharmacy records, Respondent issued a prescription for ''Valium'' [23] (a controlled substance) to M.D., dated May 24, 2013.[24] RFAAX F–8, at 18–19. The earliest patient record received from Respondent regarding M.D. was dated April 11, 2014. *See* RFAAX F–4. On April 11, 2014, M.D. completed a contact sheet, signed a ''Consent for Hormone Supplementation Therapy,'' and filled out a ''Comprehensive History Evaluation,'' but it was not fully completed. *Id.* at 1–3. For example, ''Reason for today's visit:'' was left blank and the yes or no question, ''SOCIAL HISTORY: . . . Recreational Substance: YES/NO,'' was not completed. *Id.* at 2. Respondent's records for M.D. also included ''Progress Notes,'' and an untitled document, which show that ''Respondent prescribed testosterone products for 'hair loss' on four occasions between April 11, 2014[,] and September 19, 2017.'' *Id.* at 4–5, and RFAAX G, at 10.

Dr. Chambers pointed out that the first patient record was dated ''almost a year after Respondent issued Patient M.D. a prescription for a controlled substance.'' *Id.* Moreover, Dr. Chambers observed that ''Respondent failed to document the prescription that was issued in May 2013 and failed to maintain any records relating to that prescription or relating to any medical examinations performed or observations made prior to the issuance of that prescription.'' *Id.* at 10–11.

Dr. Chambers, based on his review of the patient file for M.D., opined, and I agree, that with regard to the Vicodin prescription, ''Respondent failed to document an adequate medical history; failed to document the patient's complaint; failed to document the patient's use of other controlled substances; and failed to properly maintain medical records as required under Michigan law.'' RFAAX G, at 10. Dr. Chambers further concluded, and I agree, that ''the prescription issued by Respondent to Patient M.D. dated May 24, 2013[,] was issued outside of the standard of care in the state of Michigan and outside the usual course of professional practice.'' *Id.* at 11.

5. Patient S.C.

According to the subpoenaed pharmacy records, Respondent issued prescriptions for ''Vicodin'' [25] to S.C., dated October 12, 2013, and April 2, 2014.[26] RFAAX F–8, at 27. The earliest dated [27] patient record received from Respondent regarding S.C. was dated December 26, 2016. *See* RFAAX F–5. On December 26, 2016, S.C. signed a ''Consent for Hormone Supplementation Therapy,'' and filled out a ''Comprehensive History Evaluation,'' but it was not fully completed. *Id.* at 2–3. For example, ''Reason for today's visit:'' was left blank and the yes or no questions, ''SOCIAL HISTORY: . . . Alcohol: YES/NO,'' and ''SOCIAL HISTORY: . . . Recreational Substance: YES/NO,'' were not completed. *Id.* at 2. Respondent's records for S.C. also included ''Progress Notes,'' showing ''administration of testosterone to Patient S.C. on [ ] two occasions: December 16, 2016 and October 30, 2017.'' *Id.* at 4; RFAAX G, at 11.

Dr. Chambers pointed out that ''Respondent's patient file for Patient S.C. [does] not include *any* documentation regarding any examinations or tests performed; does not include *any* assessment or diagnosis of Patient S.C.[;] [n]or does the patient file document the issuance of the prescriptions for controlled substances [(Vicodin)] referenced above.'' *Id.* Finally, Dr. Chambers stated that ''the documents in the patient file are dated . . . years after the prescriptions for controlled substances were issued.'' *Id.*

Dr. Chambers, based on his review of the patient file for S.C., opined, and I agree, that with regard to the Vicodin prescriptions, ''Respondent failed to conduct or document an adequate physical exam; failed to document the patient's complaint; failed to document the patient's use of other controlled

[21] Dr. Chambers stated that, at the time, ''Vicodin'' was a Schedule III controlled substance. RFAAX G, at 9.

[22] There are no records related to the prescription dated June 6, 2011, in the patient file. RFAAX F–3 (Patient File for Patient M.A.).

[23] Dr. Chambers stated that ''Valium'' is a Schedule IV controlled substance. RFAAX G, at 10.

[24] There are no records related to the prescription dated May 24, 2013, in the patient file. RFAAX F–4 (Patient File for Patient M.D.).

[25] Dr. Chambers stated that, at the time, ''Vicodin'' was a Schedule III controlled substance. RFAAX G, at 11.

[26] There are no records related to the prescriptions dated October 12, 2013, and April 2, 2014, in the patient file. RFAAX F–5 (Patient File for Patient S.C.).

[27] The records contained an undated record with S.C.'s general information, such as date of birth and contact information. RFAAX F–5, at 1.

substances; and failed to properly maintain medical records as required under Michigan law.'' RFAAX G, at 12. Dr. Chambers further concluded, and I agree, that ''the two prescriptions issued by Respondent to Patient S.C. dated October 12, 2013[,] and April 2, 2014[,] were issued outside of the standard of care in the state of Michigan and outside the usual course of professional practice.'' *Id.*

6. Patient S.D.

Respondent maintained patient records for S.D. dating back to December 5, 2011. *See* RFAAX F–6 (Patient File for Patient S.D.). On December 5, 2011, S.D. documented his contact information, completed a ''Consent for Hormone Supplementation Therapy,'' and filled out a ''Comprehensive History Evaluation,'' but it was not fully completed. *Id.* at 1–3. For example, the ''CURRENT MEDICATIONS/VITAMINS'' section was blank and the question, ''SOCIAL HISTORY: . . . Recreational Substance: YES/NO,'' was not completed. *Id.* at 2. The patient file for S.D. also contained '''Progress Notes' demonstrating prescriptions for various hormones[28] issued to Patient S.D. on numerous occasions between December 5, 2011, and October 27, 2017.'' RFAAX G, at 13; F–6, at 4–9.

According to the subpoenaed pharmacy records, Respondent issued prescriptions for ''Valium'' [29] to S.C. dated March 24, 2012; June 7, 2012; March 15, 2013; April 25, 2013; May 8, 2013; December 24, 2013; April 1, 2014; and April 9, 2014. RFAAX F–8, at 1–3, 10–17, 20–23, and 44–46. There is no reference to the ''Valium'' prescriptions anywhere in Respondent's patient files for S.D. RFAAX F–6. According to Dr. Chambers, ''Valium is a benzodiazepine and a Schedule IV controlled substance [–] it is generally prescribed for the treatment of anxiety disorders or muscle spasms but is also highly diverted.'' RFAAX G, at 13.

Dr. Chambers, based on his review of the patient file for S.D., observed that ''[t]he patient file does not include any records of examinations or visits related to the [benzodiazepine] prescriptions nor does it provide any basis to assess the reason for the issuance of a benzodiazepine prescription to Patient S.D.'' *Id.* at 14. According to Dr. Chambers, ''[w]hile Patient S.D.'s patient file includes a medical history, the medical history did not include any information about any history of anxiety or other mental health issues.'' *Id.* ''The only 'complaints' listed in Patient S.D.'s file—'weight gain' and 'hair loss'—would not justify a benzodiazepine prescription.'' *Id.* Dr. Chambers also noted that ''Respondent failed to document the Valium prescriptions that were issued to Patient S.D. between March 2012 and April 2014 and failed to maintain any records relating to those prescriptions or relating to any medical examinations performed or observations made prior to the issuance of those prescriptions.'' *Id.* Per Dr. Chambers, ''[w]hile the patient 'progress notes' reference various hormone prescriptions, the benzodiazepine prescriptions are not documented in the patient file.'' *Id.*

Based on these observations, Dr. Chambers found, and I agree, that ''Respondent failed to document an adequate medical history; failed to document the patient's complaint; failed to document the patient's use of other controlled substances; and failed to properly maintain medical records as required under Michigan law.'' *Id.* Dr. Chambers further concluded, and I agree, that ''the eight [Valium] prescriptions issued by Respondent to Patient S.D. . . . were issued outside of the standard of care in the state of Michigan and outside the usual course of professional practice.'' *Id.*

7. Patient S.H.

According to the subpoenaed pharmacy records, Respondent issued a prescription to S.H. for ''Tussinex,'' a controlled substance,[30] on September 29, 2011, and prescriptions for ''Adipex/Phentermine,'' also a controlled substance, on February 12, 2013; June 10, 2013; and July 19, 2014.[31] RFAAX F–8, at 48–51; RFAAX G, at 15. The earliest dated [32] patient records received from Respondent regarding S.H. was dated March 1, 2017. *See* RFAAX F–7. On March 1, 2017, S.H. signed a ''Consent for Hormone Supplementation Therapy,'' and filled out a ''Comprehensive History Evaluation,'' but it was not fully completed. *Id.* at 2–3. For example, the yes or no questions, ''SOCIAL HISTORY: Alcohol: YES/NO . . . [and] . . . Recreational Substance: YES/NO,'' were not completed; and the ''CURRENT MEDICATIONS/VITAMINS:'' section was left blank. *Id.* at 2. Respondent's records for S.H. also include ''Progress Notes,'' which likewise do not begin until March 1, 2017. *Id.* at 4.

Dr. Chambers pointed out that ''the prescriptions issued by Respondent [to S.H.] were dated between September 2011 and July 2014—years before the first entry in the medical records.'' *Id.* ''Respondent failed to document the prescriptions that were issued to Patient S.H. between September 2011 and July 2014 and failed to maintain any records relating to those prescription[s] or relating to any medical examinations performed or observations made prior to the issuance of those prescriptions.'' *Id.*

Dr. Chambers, based on his review of the patient file for S.H., opined, and I agree, that ''Respondent failed to document an adequate medical history; failed to document the patient's complaint; failed to document the patient's use of other controlled substances; and failed to properly maintain medical records as required under Michigan law.'' RFAAX G, at 15. Dr. Chambers further concluded, and I agree, that ''the four prescriptions issued by Respondent to Patient S.H. . . . were issued outside of the standard of care in the state of Michigan and outside the usual course of professional practice.'' *Id.* at 16.

To summarize my findings above, I agree with Dr. Chambers and find substantial evidence that Respondent issued a total of twenty-one prescriptions to seven different patients without maintaining adequate records in violation of §§ 333.7303a and 333.17745 of the Michigan Compiled Laws. I also agree with Dr. Chambers and find substantial evidence that Respondent issued these twenty-one prescriptions for controlled substances outside of the usual course of professional practice and beneath the standard of care in the State of Michigan. Further, I find that Respondent sold and dispensed controlled substances to B.S. approximately 45 times without any evidence of a valid doctor-patient relationship, and I find that Respondent failed to maintain dispensing or inventory logs.

III. Discussion

A. Allegation That Respondent's Registration Is Inconsistent With the Public Interest

Under the Controlled Substances Act (CSA), ''[a] registration . . . to . . . distribute[ ] or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon

[28] The progress notes reflect the issuance of progesterone, testosterone, HCG, Armour thyroid, and others. *Id.* at 4–9.

[29] Dr. Chambers stated that, ''Valium'' is a Schedule IV controlled substance. RFAAX G, at 13.

[30] Dr. Chambers stated that, at the time, ''Tussinex'' was a Schedule III controlled substance. RFAAX G, at 15.

[31] There are no records related to the prescriptions dated September 29, 2011, February 12, 2013, June 10, 2013, or July 19, 2014, in the patient file. RFAAX F–7 (Patient File for Patient S.H.).

[32] Respondent's records contain an undated record with S.H.'s general information, such as date of birth and contact information. RFAAX F–7, at 1.

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 under such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' which is defined in 21 U.S.C. 802(21) to include a ''physician,'' Congress directed the Attorney General to consider the following factors in making the public interest determination:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing . . . controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the . . . 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 15,227, 15,230 (2003).

According to Agency decisions, I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether'' to revoke a registration. *Id.; see also Jones Total Health Care Pharm., LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016); *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482. ''In short, . . . 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; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

Under DEA's regulation, ''[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.'' 21 CFR 1301.44(e).

In this matter, while I have considered all of the Factors, the Government's evidence in support of its *prima facie* case is confined to Factors Two, Four, and Five.[33] I find the Government has satisfied its *prima facie* burden of showing that Respondent's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

B. Factors Two and/or Four—The Respondent's Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

Under Factor Two, I evaluate the registrant's ''experience in dispensing . . . with respect to controlled substances.'' 21 U.S.C. 823(f)(2). There is no evidence in the record as to the Respondent's positive dispensing experience; however, the Government has clearly established the Registrant's significant history of unlawful and dangerous dispensing practices through the text messages and patient files contained in the record.

Factor Four is demonstrated by evidence that a registrant has not complied with laws related to controlled substances, including violations of the CSA, DEA regulations, or other state or local laws regulating the dispensing of controlled substances. It is well established that a physician who engages in illegal drug distribution violates the Controlled Substances Act. *See U.S.* v. *Moore,* 423 U.S. 122, 135–36 (1975); 21 U.S.C. 841(a).

According to the CSA's implementing regulations, a lawful prescription for controlled substances 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, 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).

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act ''in the usual course of . . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Ralph J. Chambers,* 79 FR 4962 at 4970 (2014) (citing *Paul H. Volkma*n, 73 FR 30,629, 30,642 (2008), pet. for rev. denied *Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 223–24 (6th Cir. 2009)); see also *U.S.* v. *Moore,* 423 U.S. 122, 142–43 (1975) (noting that evidence established that the physician exceeded the bounds of professional practice, when ''he gave inadequate physical examinations or none at all,'' ''ignored the results of the tests he did make,'' and ''took no precautions against . . . misuse and diversion''). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a legitimate doctor-patient relationship. *Volkman,* 73 FR 30,642.

1. Allegation That Respondent Unlawfully Dispensed/Sold to B.S.

Respondent's actions with regard to B.S. demonstrate egregious dispensing experience. The definition of ''dispense'' under the CSA is ''to deliver a controlled substance to an ultimate user . . . pursuant to the lawful order of, a practitioner. . . .'' *Id.* at § 802(10). Here, Respondent delivered controlled substances to B.S. when there was absolutely no evidence of a doctor-patient relationship, exam performed, or medical diagnosis.

Agency decisions have clearly demonstrated that in order for a physician to utilize his registration to dispense controlled substances, there must be a ''valid physician-patient relationship'' and that ''[l]egally, there is absolutely no difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription.'' *Mario Avello, M.D.* 70 FR 11,695, 11,697

[33] As to Factor One, the Government alleged that Respondent holds a valid state medical license, and there is no evidence in the record of any recommendation from Respondent's ''State licensing board or professional disciplinary authority.'' *See* RFAA, at 16; 21 U.S.C. 823(f)(1). State authority to practice medicine is ''a necessary, but not a sufficient condition for registration. . . .'' *Robert A. Leslie, M.D.,* 68 FR at 15,230. Therefore, ''[t]he 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 Respondent's DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19,434, 19,444 (2011).

As to Factor Three, there is no evidence in the record that Respondent has a ''conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49,956, 49,973 (2010). Agency cases have therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

(2005) (citing *Mark Wade, M.D.,* 69 FR 7018 (2004) and *Floyd A. Santner, M.D.,* 55 FR 37,581 (1990)). B.S. admitted that she had no legitimate medical purpose for receiving the controlled substances.[34] Specifically she stated that ''she had received controlled substances and prescription[s] for controlled substances from Respondent without a legitimate medical purpose between approximately late 2001 until August 2015.'' RFAAX E, at 4. B.S. also admitted that she was taking controlled substances ''illegally.'' RFAAX E, at 5.

I agree with the Government that these actions appear to constitute ''outright drug deals.'' RFAA, at 26 (citing *James Clopton,* M.D., 79 Fed Reg. 2475, 2478 (2014)). Here, Respondent dispensed controlled substances without a legitimate medical purpose in exchange for cash and without even the façade of a medical appointment or evaluation. Respondent and B.S. did not see each other in a doctor-patient capacity—they used code names and mailbox drops to hide their illicit activity. RFAAX E, at 4, and E–4, at 94. Respondent's actions with regard to B.S. amount to those of a drug dealer. I consider these actions under Factors 2 and 4 to demonstrate that Respondent's continued registration is inconsistent with the public interest and this egregious misconduct alone warrants revocation.

2. Recordkeeping Allegations

As I found above, Respondent failed to produce either a dispensing log or an inventory. The DEA regulations require that ''[a] registered individual practitioner is required to keep records . . . of controlled substances . . . which are dispensed, other than by prescribing or administering in the lawful course of professional practice.'' 21 CFR 1304.03(b). Further, ''[e]very registrant required to keep records pursuant to § 1304.03 shall maintain, on a current basis, a complete and accurate record of each substance . . . received, sold, delivered, exported, or otherwise disposed of by him/her. . . .'' *Id.* at 1304.21(a). Similarly, Michigan law states: ''A dispensing prescriber shall include in a patient's chart or clinical record a complete record, including prescription drug names, dosages, and quantities, of all prescription drugs dispensed directly by the dispensing prescriber. . . .'' Mich. Comp. Laws Ann. § 333.17745(3) (West 2020).

Additionally, Michigan requires that a prescriber ''keep a record separate from the patient chart which contains all of the following information for controlled substances dispensed or administered by the prescriber: (a) Name of patient. (b) Name of substance and strength. (c) Quantity of substance. (d) Date dispensed or administered. (e) Name of individual who dispensed or administered.'' Mich. Admin. Code r. 338.3153(5) (2020).

The undisputed facts are that Respondent purchased hydrocodone bitartrate/acetaminophen from McKesson Corporation and dispensed it to B.S. RFAAX E, at 1–2, and *supra* Section II.D. Accordingly, I find that Respondent had a legal obligation under both federal and state law to keep a record of the controlled substances that he dispensed. *See Shawn M. Gallegos D.D.S.,* 76 FR 66,986, 66,991 (2011) (''DEA regulations state that a registered individual practitioner is required to keep records of controlled substances . . . which are dispensed.'') (internal citations omitted). However, when DI ''requested that Respondent provide [her] with dispensing records for the controlled substances he had purchased from McKesson Corporation[, he] informed [her] that no dispensing log had ever been kept.'' RFAAX E, at 3. Respondent's failure to produce a dispensing log violates 21 CFR 1304.03(b) and 1304.21(a), Mich. Comp. Laws Ann. § 333.17745, and Mich. Admin. Code r. § 338.3153.

Regarding an inventory, federal regulations require that registrants maintain ''a complete and accurate record of all controlled substances on hand. . . .'' 21 CFR 1304.11(a). Registrants must ''take a new inventory . . . at least every two years.'' 21 CFR 1304.11(c). The inventory ''must be kept by the registrant and be available, for at least 2 years from the date of such inventory . . . for inspection and copying by authorized employees of the Administration.'' 21 CFR 1304.04(a).[35] Michigan law also requires its licensees to ''make and maintain a complete and accurate inventory of all stocks of controlled substances,'' but it requires that the inventory be taken annually. Mich. Admin. Code r. §§ 338.3151–3152 (2020).

On July 13, 2016, DI requested ''that Respondent provide [her] with copies of any inventories of controlled substances.'' RFAAX E, at 3. ''[Respondent] did not provide them.'' *Id.* Respondent's inability to produce a biennial inventory constitutes a violation of the requirement to maintain such an inventory. *See Rene Casanova, M.D.,* 77 FR 58,150, 58,160 (2012). As such, Respondent's failure to produce an inventory violates 21 CFR 1304.11(c) and Mich. Admin. Code r. §§ 338.3151–3152.

In sum, I find that Respondent's failure to provide a dispensing log and an inventory is relevant to public interest Factors Two and Four. I find that the Government has established that Respondent was not in compliance with several state and federal laws—including 21 CFR 1304.03(b), 1304.11(c) and 1304.21(a), Mich. Comp. Laws Ann. § 333.17745, and Mich. Admin. Code r. §§ 338.3151–3153.

3. Allegation That Respondent Issued Prescriptions for Controlled Substances Outside the Usual Course of the Professional Practice and in Violation of Michigan Law

My full factual findings regarding the standard of care in Michigan (including the Michigan Laws reflecting the standard of care) are set forth above. *See supra* Section II.C. In short, it is the law in Michigan that a physician ''shall keep and maintain a record for each patient for whom he or she has provided medical services, including a full and complete record of tests and examinations performed, observations made, and treatments provided.'' Mich. Comp. Laws Ann. § 333.16213 (West 2020). Additionally, ''[b]efore prescribing or dispensing a controlled substance to a patient, a licensed provider shall ask the patient about other controlled substances the patient may be using . . . [and] record the patient's response in the patient's medical or clinical record.'' Mich. Comp. Laws Ann. § 333.7303a(3) (West 2020).

As set forth more fully in the factual findings section above, the Government established through a credible expert witness that Respondent violated §§ 333.16213 and 333.7303a of the Michigan Compiled Laws and issued prescriptions outside of the usual course of professional practice and beneath the standard of care for the State of Michigan as follows:

—He failed to maintain records regarding other controlled substances that patients were taking with regard to patients D.K., F.C., M.A., M.D., S.C., S.D., and S.H.

—He failed to take or document a complete medical history with regard to patients D.K., M.A., M.D., S.D., and S.H.

[34] Moreover, the text messages between Respondent and B.S. demonstrate that B.S. ''was not seeking the drugs for the purpose of treating a legitimate medical condition, but rather, for the purpose of abusing them.'' *James Clopton, M.D.,* 79 FR 2475, 2478 (2014).

[35] The OSC does not allege that Respondent violated 21 CFR 1304.04 as part of its recordkeeping allegations and therefore I am making no findings related to this section, but am instead including this reference in order to support my findings related to the alleged violation of 21 CFR 1304.11.

—He failed to document the patient's complaint with regard to patients D.K., F.C., M.A., M.D., S.C., S.D., and S.H.

—He issued prescriptions without first having any patient files or records of examinations performed with regard to patients D.K., F.C., M.A., M.D., S.C., and S.H.[36]

—He issued prescriptions without having any record of an examination performed regarding or any medical history regarding the need for the specific prescriptions at issue with regard to patient S.D.

See supra Section II.F. In total, Respondent issued twenty-one prescriptions outside of the standard of care including: One prescription to D.K, four prescriptions to F.C., one prescription to M.A., one prescription to M.D., two prescriptions to S.C., eight prescriptions to S.D., and four prescriptions to S.H. *Id.* Each of those twenty-one prescriptions also violated § 333.16213 and § 333.7303a of the Michigan Compiled Laws.

Based on my analysis of Factors Two and Four in considering these violations, I find that Respondent's continued registration would be inconsistent with the public interest.

C. Factor Five—Such Other Conduct Which May Threaten Public Health and Safety

Under Factor Five, the Administrator is authorized to consider ''[s]uch other conduct which may threaten the public health and safety.'' 5 U.S.C. 823(f)(5). Although Factor Five is broad, DEA decisions have qualified its breadth by limiting the considerations made under that factor to those where there is ''a substantial relationship between the conduct and the CSA's purpose of preventing drug abuse and diversion.'' *Zvi H. Perper, M.D.,* 77 FR 64,131, 64,141 (2012) (citing *Tony T. Bui,* 75 FR 49,979, 49,988 (2010)). As the Agency has previously stated, '''[c]areless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify' the revocation of an existing registration or the denial of an application for a registration.'' *Lon F. Alexander, M.D.,* 82 FR 49,704, 49,725 n.43 (2017) (quoting *Paul J. Caragine, Jr.* 63 FR 51,592, 51,601 (1998)).

Here, Respondent continued to provide controlled substances to B.S. illegally despite indications of addiction and abuse. *See,* RFAAX E–4, 94–95, 100–01. Respondent was ''starting to worry'' about when she would get her pills; she begged Respondent to ''PLEASE call in a script,'' so that she did not have to ''check [into] a treatment center;'' she claimed she ''REALLY need[ed] [the pills];'' and she requested that Respondent ''put [the pills] in the mailbox so [her brother] does not see.'' *Id.* at 94–95, 100–01. These texts reflect a concerning ''need'' for the pills and a desire to conceal their existence from her family. The continued provision of pills to B.S. despite B.S. having demonstrated that she was abusing the controlled substances demonstrates Respondent's disregard for B.S.'s health and safety. *See e.g. Trenton F. Horst, D.O.,* 80 FR 41,079, 41,090 (2015) (''Respondent's behavior [was] also troubling under factor five . . . [because] Respondent continued prescribing hydrocodone . . . to [his girlfriend] despite knowing that [his girlfriend] regularly abused controlled substances . . .'').

''[A] DEA registrant is obligated at all times to act in the public interest.'' *Peter F. Kelly, D.P.M.,* 82 FR 28,676, 28,688 (2017). In April 2017, B.S. died, and ''[t]he Office of the Medical Examiner of Oakland County, Michigan, determined that the cause of death was medication overdose.'' RFAAX E, at 5. Although there is no evidence that Respondent was in any way associated with the medication that led to B.S.'s overdose and death, her death reinforces the import of the CSA's requirement that registrants act in the public interest. Further, in providing B.S. controlled substances to fuel her drug addiction, Respondent demonstrated a reckless disregard for public health and safety. The mere fact that Respondent did not provide the controlled substances that led to her overdose does not negate the very clear evidence that he knew or should have known that he was endangering her life by fueling her addiction.

As found above, the Government's case establishes by substantial evidence that Registrant issued controlled substance prescriptions without a legitimate medical purpose and outside the usual course of professional practice and beneath the standard care in the State of Michigan. I conclude that Registrant engaged in egregious misconduct, which supports the revocation of his registration. *See Wesley Pope,* 82 FR 14,944, 14,985 (2017). Overall, it is clear that the Government has established a *prima facie* case that Respondent's continued registration is inconsistent with the public interest.

IV. Sanction

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 no effort to establish that he can be trusted 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 argument submitted to determine whether or not a respondent 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. Kennnedy, 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

[36] For certain patients, Dr. Chambers opined that the failure to include any documentation in the patient files ''strongly indicates that Respondent failed to create or maintain *any* records contemporaneously with the issuance of the prescription[s].'' RFAAX G, at 12. 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).

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.'' *Jeffrey Stein, M.D.,* 84 FR 46,968, 49,972 (2019); *see also Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

Here the Respondent responded to the Government's Order to Show Cause by waiving his right to a hearing—no written brief or other explanation of his behavior accompanied the waiver of his right to a hearing. RFAAX B; RFAA, at 1. In other words, Respondent did not avail himself of the opportunity to refute the Government's *prima facie* case, nor did he attempt to explain why, in spite of his conduct, he can be entrusted with a registration. There is no statement from Respondent in the record. Nor is there any indication that Respondent has accepted any responsibility for his actions,[37] much less the ''unequivocal acceptance of responsibility [that is required] when a respondent has committed knowing or intentional misconduct.'' *Mohammed Asgar, M.D.,* 83 FR 29,569, 29,572 (2018) (citing *Lon F. Alexander, M.D.,* 82 FR 49,704, 49,728). Such silence weighs against the Respondent's continued registration. *Zvi H. Perper, M.D.,* 77 FR at 64,142 (citing *Medicine Shoppe,* 73 FR at 387); *see also Samuel S. Jackson,* 72 FR at 23,853.

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. The underlying issues in this case (unlawful dispensing, recordkeeping violations, and prescribing beneath the standard of care, and failure to maintain complete patient records) fall squarely within the purview of the CSA and revocation as a sanction is calculated to deter similar acts from others. *See Leo R. Miller, M.D.,* 53 FR 21,931, 21,932 (1988) (describing revocation as a remedial measure ''based upon the public interest and the necessity to protect the public from those individuals who have misused controlled substances or their DEA Certificate of Registration, and who have not presented sufficient mitigating evidence to assure the Administrator that they can be trusted with the responsibility carried by such a registration.''). There is simply no evidence that Respondent's egregious 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 sanction.

I agree with the former Assistant Administrator of the Diversion Control Division, that Respondent's proposed Corrective Action Plan provides no basis for me to discontinue or defer this proceeding. Its insufficiencies include Respondent's failure to accept responsibility, to institute adequate remedial measures, and to convince me to entrust him with a registration. 21 U.S.C. 824(c)(3).

I will therefore order that Respondent's registration be revoked and that any pending applications be denied as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FC2341876 issued to Salvatore Cavaliere, D.O. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Salvatore Cavaliere, D.O. to renew or modify this registration, as well as any other pending application of Salvatore Cavaliere, D.O. for registration in Michigan. This Order is effective August 28, 2020.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–16388 Filed 7–28–20; 8:45 am]

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[37] Although it is not evidence of Respondent's acceptance of responsibility, I note that Respondent appears to have been cooperative with DI during the July 13, 2016 search of Respondent's registered address. RFAAX E, at 3.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 18–28]

Kaniz F. Khan-Jaffery, M.D.; Decision and Order

I. Procedural History

On April 12, 2018, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension Order (hereinafter collectively, OSC) to Kaniz F. Khan-Jaffery, M.D. (hereinafter, Respondent), of Absecon, New Jersey. Administrative Law Judge (hereinafter, ALJ) Exhibit (hereinafter, ALJX) 1, (OSC) at 1. The OSC informed Respondent of the immediate suspension of her DEA Certificate of Registration No. BK9710939 pursuant to 21 U.S.C. 824(d) ''because . . . [her] continued registration constitute[d] an imminent danger to the public health and safety.'' *Id.* The OSC also proposed the revocation of Respondent's Registration pursuant to 21 U.S.C. 824(a)(4) and the denial of ''any pending applications for renewal or modification of such registration, because [her] continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.*

Specifically, the OSC alleged that Respondent issued prescriptions for controlled substances to six individuals outside the usual course of the professional practice and beneath the standard of care for the State of New Jersey in violation of 21 CFR 1306.04(a) and N.J. Stat. §§ 24:21–15.2 and 45:9–22.19. OSC, at 2–5.

On April 12, 2018, based on his preliminary finding that Respondent issued multiple prescriptions to one individual without a legitimate medical purpose, and to five individuals, while ignoring inconsistent urine screens that indicated abuse or diversion of controlled substances, the former Acting Administrator concluded that Respondent's ''continued registration . . . [was] inconsistent with the public interest.'' OSC, at 5. Citing 21 U.S.C. § 824(d), he also made the preliminary finding that Respondent's continued registration during the pendency of proceedings ''would constitute an imminent danger to the public health or safety because of the substantial likelihood that [Respondent] would continue to issue prescriptions for controlled substances, which would result in the abuse or diversion of controlled substances.'' *Id.*

Pursuant to 21 U.S.C. 824(d) and 21 CFR 1301.36(e), the former Acting Administrator immediately suspended Respondent's Certificate of Registration and authorized the DEA Special Agents and Diversion Investigators serving the OSC on Respondent to place under seal or to remove for safekeeping all controlled substances Respondent possessed pursuant to the immediately suspended registration. *Id.* The former Acting Administrator also directed those DEA employees to take possession of Respondent's Certificate of Registration BK9710939. *Id.*

The OSC notified Respondent 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.* (citing 21 CFR 1301.43).

By letter dated May 1, 2018, Respondent timely requested a hearing. ALJX 2 (Request for Hearing), at 1. The matter was placed on the docket of the

Office of Administrative Law Judges and assigned to Administrative Law Judge Charles W. Dorman (hereinafter, ALJ). On May 3, 2018, the ALJ established a schedule for the filing of prehearing statements. ALJX 3 (Order for Prehearing Statements), at 1, 4. The Government filed its Prehearing Statement on May 15, 2018, and Respondent filed its Prehearing Statement on May 25, 2018. ALJX 4 (hereinafter, Govt Prehearing) and ALJX 5 (hereinafter, Resp Prehearing). On June 6, 2018, the ALJ issued his Prehearing Ruling that, among other things, set out twenty-two Stipulations already agreed upon and established schedules for the filing of additional joint stipulations and supplemental prehearing statements, which were filed by both the Respondent and the Government on August 8 and 15, 2018, respectively. ALJX 9 (Prehearing Ruling), at 1–9; ALJX 21 (hereinafter, Resp Supp Prehearing); ALJX 22 (hereinafter, Govt Supp Prehearing). Additionally, on July 18, 2018, Respondent filed a Motion to Strike and for Recommendation for Interim Reinstatement, alleging among other things that the OSC mis-referenced N.J.S.A. 24:21–15.2, because the statute did not go into effect until May 16, 2017. ALJX 12 (Resp Motion to Strike), at 2–3. The Government filed an opposition on July 23, 2018. ALJX 15 (Govt Opposition). The ALJ denied Respondent's Motion to Strike, finding that Respondent's argument is fact-based and is ''best left for either resolution between the Parties or at the hearing.'' ALJX 17 (Motion to Strike Denial), at 2.[1] I have reviewed and agree with the procedural rulings of the ALJ during the administration of the hearing.

The hearing in this matter spanned five days.[2] The Recommended Rulings, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (hereafter, RD) is dated January 31, 2019. Both parties filed exceptions to the RD on March 13, 2019. ALJ Transmittal Letter, at 1. On March 20, 2019, the ALJ transmitted his RD, along with the certified record, to me. *Id.*

Having considered this matter in the entirety, I find that Respondent issued twenty-three prescriptions beneath the applicable standard of care and outside of the usual course of the professional practice in New Jersey, in violation of federal law, and that Respondent also committed violations of state law.

I issue this Decision and Order based on the entire record before me. 21 CFR 1301.43(e). I make the following findings of fact.

II. Findings of Fact

A. Respondent's DEA Registration

Respondent is registered with the DEA as a practitioner in schedules II through V under DEA Certificate of Registration No. BK9710939, at the registered address of 1129 North New Road, Absecon, New Jersey, 08201. Government Exhibit (hereinafter, GX) 1 (Respondent's Certificate of Registration). This registration expires on December 31, 2020. *Id.* This registration was suspended pursuant to the Immediate Suspension Order dated April 12, 2018. OSC, at 1.

B. The Government's Case

The Government's documentary evidence consisted primarily of medical records for six individuals treated by Respondent between January 30, 2015, and October 18, 2017, which included the records for one undercover Special Agent. The Government called three witnesses; a DEA Special Agent, who posed undercover as patient A.D. on six occasions (hereinafter, the UC); a DEA Diversion Investigator (hereinafter, DI), who participated in the investigation of Respondent; and an expert witness, Dr. Andrew Kaufman. RD, at 7–10.

The UC testified about her role in the investigation of Respondent and her role-related and investigatory experience. Tr. 36–38. On each of the six occasions in which the UC visited Respondent, she wore a recording device that provided audio and video recordings of each visit.[3] *Id.* at 38. Those video recordings and transcripts of the recordings are provided in Government's exhibits.[4] GX 6–11 (Video Files of the UC's visits with Respondent on October 17, 2016, November 23, 2016, December 22, 2016, January 19, 2017, March 7, 2017, and April 4, 2017, respectively); GX 12–17 (Transcripts of UC visits). The Government also provided copies of the UC's patient file for her six visits and the prescriptions issued to her by Respondent. GX 18, 19, 21, 23, 25, 27, 29 (patient file and visit notes); GX 20, 22, 24, 26, 28 (copies of prescriptions issued to the UC by Respondent). Having read and analyzed all of the record evidence, including the video recordings of the UC's visits, I agree with the ALJ's conclusion that the UC's relevant testimony was ''sufficiently objective, detailed, plausible, and internally consistent,'' and therefore, credible.[5] RD, at 7–8.

The Government presented the testimony of a DI assigned to the DEA Camden Resident Office, who participated in the administrative investigation of Respondent. Tr. 125–26. The DI testified that she first became aware of Respondent while investigating a pharmacy. *Id.* at 126; *see also* RD, at 8. She testified that one of the pharmacy's suppliers had ''seen that pharmacy had an unusually high volume of narcotic prescriptions being filled, and that [Respondent] was the No. 1 prescriber for that pharmacy and for those controlled substances.'' Tr. 127. The DI testified that an administrative subpoena was issued to Respondent to obtain complete patient records for seventy-four named individuals, who were identified based on red flags for diversion, and another subpoena was issued for updates on thirty of those individuals named in the earlier subpoena. Tr. 128, 129; *see* GX 4 (first administrative subpoena issued November 3, 2017) and GX 5 (second administrative subpoena served April 13, 2018); *see also* RD, at 8. The

[1] It is noted that on November 15, 2018, the ALJ sent notice to the parties that I had concluded that the DEA ALJs had not been properly appointed under Article II of the Constitution at the time of the hearing and the ALJ set a deadline to bring a challenge based on the Appointments Clause, which the ALJ then extended after the Respondent requested clarification regarding the implications of a challenge. ALJX 51 (Notice); ALJX 52 (Respondent Letter); ALJX 53 (Response and Extension). Respondent then sent a letter to me requesting indemnification for the cost of the initial hearing so that she could request a new hearing and also moved for an adjournment of the proceedings until I responded to her request for indemnification. ALJX 55 (Respondent's Letter to the Acting Administrator). The ALJ denied the Adjournment, finding that he had extended the deadline already once and that Respondent had waived her opportunity to make an Appointments Clause challenge. ALJX 56 (Order Denying Respondent's Request for Adjournment). I agree with the ALJ that Respondent's Appointments Clause challenge did not comply with the terms of the ALJ's notice authorizing such a challenge. Further, Respondent made no further argument about the Appointments Clause in either her Posthearing Brief or her Exceptions to the RD; therefore, I find that Respondent waived her right to challenge the ALJ's appointment.

[2] Hearings were held in New York, New York on September 17–21, 2018.

[3] The UC testified that during her final visit with Respondent, the recording device malfunctioned and provided only an audio recording of the visit. Tr. 38, 71; *see also* RD, at 7.

[4] The UC testified that the transcripts of the recordings were accurate depictions of the visits, with the exception of the transcript in GX 12 at page 8, where the UC testified that she told Respondent that she got her medicine in ''New York,'' rather than ''Newark.'' Tr. 44, 50; RD, at 7.

[5] The ALJ noted that he found some irrelevant testimony of the UC confusing, but he also noted that the testimony does not detract from her overall credibility. RD, at 8 (citing tr. 81–88). I agree that the topic was irrelevant. Further, I determine that due to the Government's objections regarding law enforcement sensitivity during the hearing, it does not appear to me that the facts were fully explored on this topic, and therefore, I do not find the testimony confusing. I agree with the ALJ that this testimony does not detract from the UC's credibility.

Government's evidence includes six patient files obtained through those subpoenas. GX 29, 84, 130, 175, 259, 344.

I agree with the ALJ that the DI's testimony was ''sufficiently objective, detailed, plausible, and internally consistent.'' RD, at 8. Although the ALJ ultimately concluded that D.I.'s testimony was unnecessary, I credit her testimony regarding the Agency's initiation of an investigation into Respondent's practice and the results of the subpoenas to the extent that they provide the foundations of this administrative matter.

The Government's expert witness, Professor Andrew Kaufman, M.D., is a professor of anesthesiology at Rutgers University, and testified that he has ''extensive clinical responsibilities, seeing patients in two offices'' in New Jersey. Tr. 155–57. He also teaches medical students and residents and serves as the Executive Director of the New Jersey Society of Interventional Pain Physicians. *Id.* at 157–58; GX 345 (Curriculum Vitae of Dr. Kaufman); *see also* RD, at 8. The ALJ accepted Dr. Kaufman as ''an expert in the treatment of pain with controlled substances in the State of New Jersey.'' RD, at 8; tr. 168.[6] The matters about which Dr. Kaufman testified included his review and standard-of-care analysis of medical records belonging to six of Respondent's patients, including the UC. Tr. 171–72. In forming his opinion, he also reviewed the video tapes and one audio tape of the UC visits with Respondent. *Id.* at 169.

The ALJ found, and I agree, that Dr. Kaufman's testimony was ''presented in a professional, candid, and straightforward manner'' and ''was sufficiently objective, detailed, plausible, and internally consistent,'' and therefore credible.[7] RD, at 10.

[6] I agree with the ALJ in overruling the objection of Respondent's counsel to Dr. Kaufman's expertise, which counsel appeared to be basing on the grounds that Dr. Kaufman only treats approximately ten percent of his patients with controlled substances, and that, given his preference for not prescribing controlled substances, his experience is not relevant to the case. RD, at 8; tr. 167–68. I find that the percentage of patients to whom controlled substances have been prescribed by Dr. Kaufman has no bearing on his expertise in the treatment of pain with controlled substances or the applicable standard of care in the State of New Jersey.

[7] However, in comparing Dr. Kaufman's testimony with the testimony of Dr. Epstein, Respondent's expert witness, the ALJ frequently gave Dr. Epstein's testimony more weight, because ''Dr. Epstein supported his opinions with more well-reasoned analysis and explanation than did Dr. Kaufman.'' RD, at 17; 10 n1. I disagree with the ALJ's decision to give Dr. Epstein's testimony more weight as explained in the standard of care section below. *See infra* II(E)(1).

C. The Respondent's Case

Respondent presented the testimony of four witnesses at the hearing, including her own. The first witness, Dr. Lawrence J. Epstein, M.D., has treated pain patients for thirty years and is an Associate Professor of Anesthesiology and Neurology at the Icahn School of Medicine, Mt. Sinai Hospital, and has held professorial appointments and staff positions at multiple hospitals in New York. RD, at 11; *see also* tr. 687–97. Dr. Epstein is also the Chair of the New York State Board of Medicine, which is responsible for all medical licensure in that state and has input into all medical policy for the state. RD, at 11; tr. 691–93. Dr. Epstein was involved in writing New York's law concerning its Prescription Monitoring Program. RD, at 11; tr. 696. Dr. Epstein testified that he is familiar with the standard of care for prescribing pain medicine and has published articles and spoken publicly about prescribing opioids, including the ''over-prescribing'' of opioids since about 2008 or 2009. RD, at 11 (citing tr. 699). Dr. Epstein submitted a written report on his assessment of the medical files of the patients at issue in this proceeding. ALJX 5, Attachment 1.

Dr. Epstein holds a license to practice medicine in New Jersey since ''somewhere between'' 1986–88, but has never practiced there, and his license is inactive. Tr. 703; RD, at 11.[8] He testified that he has read some of the New Jersey statutes concerning pain management, but that the standard of care does not include the statutes, and it differs by region and the number of patients a doctor sees on a daily basis. RD, at 12; tr. 704, 708, 711. With respect to prescribing opioids, Dr. Epstein testified there is a nationwide standard of care, which he applied in evaluating this case. RD, at 12; tr. 722, 729.

The ALJ admitted Dr. Epstein as an expert in pain management practice in ''standard of care, on proper medical procedures with respect to pain management, and the appropriate use of controlled substances in medical practice.'' RD, at 12 (citing tr. 702, 730). The Government objected on the ground that he lacked experience and knowledge of the standard of care in New Jersey. RD, at 12; tr. 716–17, 730. The ALJ found, and I agree, that Dr. Epstein's testimony regarding several aspects of the case was ''concerning.'' RD, at 14. In particular, the ALJ found that his testimony about Patient J.C.'s inconsistent urine screens did not withstand close scrutiny, because the patient records did not support his statements. *Id.* at 14–15 (citing tr. 1583–84). Dr. Epstein also testified that the UC was an established patient by the time Respondent issued her a prescription for controlled substances on the second visit, which the ALJ believed was a ''bit of a stretch.'' RD, at 15 (citing tr. 1454). The ALJ also found that Dr. Epstein placed too much weight on the UC's previous medical records, about which even the Respondent ''expressed concern.'' RD, at 15 (citing GX 13, at 6–7; RX 7, at 2). Finally, the ALJ found that Dr. Epstein's testimony regarding Patient A.P.'s alcohol counseling was not based on the evidence. RD, at 15 (citing tr. 1542–44; tr. 1640–41; GX 80). Despite these concerns, the ALJ found that ''Dr. Epstein's testimony was compelling in several aspects.'' RD, at 15. The ALJ credited Dr. Epstein's opinion about urine screens being positive for alcohol metabolites and documentation of counseling after inconsistent urine screens. *Id.* at 15–16. In all, the ALJ stated, ''After having closely observed Dr. Epstein during his testimony, as well as having attentively listened to his testimony during the hearing, I have carefully reviewed the transcript of his testimony. I find that Dr. Epstein's testimony was sufficiently objective, detailed, plausible, and internally consistent to be considered credible in this Recommended Decision.'' *Id.* at 16. I defer to the ALJ's assessment of Dr. Epstein's overall credibility, and in particular, the ALJ's observations of his testimony. However, as further explained herein, I do not concur with the ALJ's finding that Dr. Epstein's testimony regarding the applicable standard of care in New Jersey was more credible than Dr. Kaufman's regarding prescribing after inconsistent urine screens. RD, at 16.

Respondent testified on her own behalf. Tr. 775–1120. She testified that she earned her medical degree in Pakistan and completed a neurology residency and a fellowship in pain management at Louisiana State University. RD, at 17; tr. 784–87. In 2008, Respondent began practicing pain management in New Jersey, and worked for two years at a neurosurgeon's office, then she worked with her husband's practice, as well as consulted in pain management at AtlantiCare Regional Medical Center. Tr. 788–89, 793–94. Respondent testified as to her standard pain management practice with respect to the patients in question, including her use of monthly urine screens, her practice of obtaining MRIs before prescribing controlled substances, her use of an electronic recordkeeping

[8] The RD noted 1980, but in the transcript, Dr. Epstein hesitated and then said 86–88. Tr. 703.

program called eClinical (hereinafter, eClinical), and her counseling practice. *Id.* at 799–805, 827, 882, 991–92, 933–35, 1040; *see also* RD, at 18–19. She also testified specifically to her treatment of the six patients. RD, at 19–22. She testified that she sees fifty to fifty-five patients per day and bills about ten minutes per patient. Tr. at 985, 988. Additionally, she testified to the controls that she has put in place in her practice. Specifically, she requires a referral from a physician to make an appointment. *Id.* at 815. She also requires all of her patients to take urine drug screens on a monthly basis, which she does at her own volition and expense, despite the burden it imposes. *Id.* at 799–800.

The ALJ found, and I agree, that ''there were several aspects of [Respondent's] testimony that were problematic.'' RD, at 22. He found that her testimony regarding Patient L.M.'s urine screen showing Suboxone was not credible. *Id.* at 22–23. Respondent hypothetically discussed the possibility that the patient had received the Suboxone at a hospital or rehabilitation facility after running out of her medication, but ''two of the three times L.M. screened positive for Suboxone, she was also positive for oxycodone,'' and the other time the laboratory did not test for oxycodone. RD, at 22–23 (citing tr. 1095–96, 1099, 1100; GX 175, at 139, 141, 144). If the patient had run out of oxycodone in order to receive the Suboxone for withdrawal, she would not have tested positive for it. The ALJ also found that Respondent's ''explanation of why she did not conduct a physical examination of [UC's] shoulder to be unconvincing.'' RD, at 23. Specifically, Respondent testified at one point that a physical exam would be painful because of arthritis, but she also testified that she observed the UC's ''range of motion to be 'pretty good.' '' *Id.* at 23 (citing tr. 824, 1065). He found that her testimony about L.M.'s urine screen that was positive for fentanyl was also inconsistent. RD, at 23. Finally, he found that her testimony regarding the UC's diagnosis of arthritis was ''inconsistent with her own records.'' *Id.* at 23–24. The ALJ stated:

> While the five concerns discussed above detract from [Respondent's] overall credibility, I find that most of her testimony was sufficiently objective, detailed, plausible, and internally consistent. I do not find that [Respondent] was engaged in intentional fabrication . . . . Therefore, I merit her testimony to be credible in all non-contested matters in this Recommended Decision.

Id. at 24.

Although I believe that the ALJ analyzed the Respondent's testimony thoroughly and honestly, and I defer to his determination of credibility as to Respondent's demeanor, I do not believe that there is practical value in meriting her testimony in non-contested matters for purposes of this proceeding, particularly because she did not offer much, if any, acceptance of responsibility, as further discussed in the sanctions section herein. *See infra* IV. The ALJ credited Respondent's testimony that she had counseled her patients for their urine screen results—a fact which is contested in this matter. *See* RD, at 43 (citing tr. 853, 974–75, 981, 993–94, 1336, 1344–45, 1354). I found additional instances of inconsistencies in Respondent's testimony that undermine her credibility as well. For example, she testified that she relied on the UC's MRI in lieu of a physical exam to form her diagnosis, but the transcript demonstrates that Respondent was repeatedly confused about whether or not she had seen the MRI. *See infra* II(F)(1); GX 14, at 11, 13; GX 15, at 5; GX 16, at 9. Respondent also testified that when L.M. tested positive for Suboxone, she had called the lab and the lab had said to recheck the urine ''[a]nd I tested her again; she didn't come back positive the next time.'' Tr. 857. This description of events is undermined by the evidence on the record that shows that L.M. testified positive three times in a row for Suboxone and by Respondent's own subsequent testimony. *See infra* II(F)(5); tr. 1092–95.

Respondent also presented the testimony of Dr. Thomas Gutheil as an expert in medical documentation and medical records. RD, at 24–28; tr. 1123–1325. Dr. Gutheil is a practicing psychiatrist and professor of psychiatry at Harvard Medical School and lectures on electronic medical recordkeeping, among other medical subjects. RD, at 24; tr. 1123–1124. He testified that as a hospital records committee chairperson reviewing medical records for quality assurance for many years, he developed his study of medical recordkeeping, and has published several peer review articles on medical documentation, and lectures on the subject worldwide. RD, at 24–25. He also provided a written report, which was submitted in Respondent's initial Prehearing statement. ALJX 5, Attachment 2. Dr. Gutheil testified that he is not licensed to practice medicine in New Jersey, but he follows the developments of medical documentation in New Jersey, and he reviewed some of the New Jersey regulations and laws about medical recordkeeping in preparation for the hearing. RD, at 28 (citing tr. 1135–36, 1136–38). He also testified that he was not familiar with Respondent's recordkeeping eClinical when he wrote his report, and that he did not know which version of eClinical Respondent used in her practice. RD, at 28; tr. 1155, 1281–82.

The ALJ accepted Dr. Gutheil as an expert in ''medical documentation and medical records.'' RD, at 28; tr. 1132. He also found Dr. Gutheil's testimony was presented in a professional, candid, straightforward manner, and it was ''helpful in understanding the standards of medical documentation and electronic medical recordkeeping.'' RD, at 28. He merited it as sufficiently objective, detailed, plausible and internally consistent to be fully credible. *Id.* Overall, I agree that Dr. Gutheil's testimony was credible, but I do not believe that the use of the word ''standards'' in the ALJ's assessment is appropriate, because Dr. Gutheil testified on numerous occasions that his testimony had nothing to do ''with issues of legal standards and so forth or even medical care. And that's not my subject.'' Tr. 1138.[9] Additionally, the ALJ clarified to Respondent's attorney during the hearing that he was not accepting Dr. Gutheil as an expert in the standard of care. *Id.* at 1157–1161, 1216–1217 (ALJ stating that he was ''not going to allow the question, because it's going to a standard. I don't—what sort of standard?'' Respondent's attorney responded, ''Is there a standard for medical documentation?'' The ALJ then sustained the Government's objection that no standard was mentioned in Dr. Gutheil's report); *accord* tr. 1239, 1241, 1250, 1270, 1291, 1294–97, 1308. To the extent that the ALJ permitted limited testimony differentiating a standard of recordkeeping from the standard of care, it seems largely irrelevant to the underlying charges of prescribing beneath the applicable standard of care in the State of New Jersey. *See* OSC, at 2–5. I agree with the ALJ that Dr. Gutheil's testimony supported the reasons why documentation is important ''to create a record for the continuity of care, including care provided by subsequent practitioners; create a permanent record about the patient's medical history; aid the practitioner in planning treatment; and to prevent liability.'' RD, at 116 (citing tr. 1214, 1272, 1280–81, 1287 and ALJX

[9] Respondent agreed that ''Dr. Gutheil was not qualified to, and could not, testify to the standard of care.'' Resp Exceptions, at 16 (citing Tr. 1158–1159).

60 (Respondent's Posthearing Brief (hereinafter, Resp Posthearing), at 16)). However, I find that overall, Dr. Gutheil's testimony is largely irrelevant to this proceeding, because he did not testify about the applicable standard of care.[10] His testimony was presented to mitigate the Respondent's inadequate recordkeeping. *See* Resp Posthearing, at 17 (arguing that Dr. Gutheil's testimony established that ''there is always something more that a physician could write in a chart; if a physician spent all her time writing, there wouldn't be any time to see the patients.'' (citing tr. 1215)). This mitigating testimony may have been persuasive had Respondent accepted responsibility for her actions and demonstrated how she would prevent the recurrence of her violations of law as discussed in *infra* Section IV.

Finally, Respondent offered the testimony of Patient J.C., who was one of the six patients whose records were at issue in this proceeding. Tr. 1327–69; RD, 28–31. J.C. testified that Respondent had been treating him since 2016 for neuropathy in his feet and pain in his lower back due to a pinched nerve and degenerative disc disease in his lower back. RD, at 28; tr. 1328–29, 1330. He testified generally about Respondent's care, including her counseling on his inconsistent urine screens. RD, at 29–30. The ALJ found several ''discrepancies,'' which ''detract from J.C.'s overall credibility.'' *Id.* at 30. The ALJ meticulously matched J.C.'s statements with his patient records and found that he inaccurately testified that Respondent had first prescribed tramadol to him after his inconsistent urine screen to help alleviate his pain, when the records demonstrated that she had prescribed tramadol on his second visit. *Id.* at 30 (citing tr. 1343–44, 1354; ALJX 45, at 2). He also determined that J.C. had inaccurately testified that his second inconsistent urine screen occurred because of a cancelled appointment, whereas the record demonstrated that the inconsistent screen had occurred ''on June 20, 2017, and he had filled the previous prescription for 120 oxycodone tablets on May 22, 2017, 30 days before he provided his urine sample.'' RD, at 30 (citing tr. 1355–57, 1367; ALJX 45 (Spreadsheet of PMP Data), at 2). Despite the inconsistencies, the ALJ found that ''he testified in a professional, candid, and straightforward manner,'' and that his testimony ''[w]as sufficiently objective, detailed, plausible, and internally consistent.'' RD, at 30–31. Therefore, the ALJ merited the testimony as ''fully credible concerning whether [Respondent] counseled him regarding his three inconsistent urine screens.'' *Id.* I defer to the ALJ's assessment of J.C.'s demeanor and his professionalism, but I struggle with accepting his finding that, despite the large inconsistencies that he, himself, found, J.C.'s testimony was ''consistent.'' *Id.* However, because I am basing my findings regarding J.C. on Respondent's failure to document her counseling, as opposed to her failure to counsel, I find that his testimony regarding counseling does not affect my Decision and Order. *See infra* II(E)(3)(a).

D. The ALJ's Conclusions of Law Regarding New Jersey Statutes and Regulations

The Government alleged that Respondent violated a New Jersey statute and two New Jersey regulations. *See* OSC, at 2; Govt Prehearing, at 4, 5. Overall, the ALJ did not sustain the Government's allegations of violations of the New Jersey statute and regulations, ''[b]ecause neither Dr. Kaufman nor Dr. Epstein testified that [Respondent] had violated any particular New Jersey statute or regulation in issuing any of the 17 prescriptions.'' RD, at 139. The Government filed Exceptions to the Recommended Rulings, Conclusions of Law, and Decision of the Administrative Law Judge, in which it argued that the ALJ's findings were in error, and that the error led the ALJ to credit Dr. Epstein's testimony over Dr. Kaufman's and to find ''Respondent's violations to be less numerous and egregious [than] they in fact were, and this finding contributed to his recommendation of a sanction less than revocation.'' Govt Exceptions, at 4. The Respondent also filed Exceptions to the Recommended Decision (hereinafter, Resp Exceptions), in which she specifically argued that the statutory language was essential to understanding that a physical exam under New Jersey law was only required ''as appropriate.'' Resp Exceptions, at 8–9. Although on close examination of the violations that the ALJ sustained, the effect of his finding regarding New Jersey law is potentially not as critical as the Government argued, I am addressing this issue at the outset because the law does lay a foundation for the applicable standard of care in New Jersey in this case.

1. New Jersey Administrative Code § 13:35–7.1A

New Jersey Administrative Code § 13:35–7.1A requires in relevant part that practitioners shall not dispense drugs or issue prescriptions (not solely controlled substances) ''without first having conducted an examination, which shall be appropriately documented in the patient record.'' N.J. Admin. Code § 13:35–7.1A (West 2020) (effective September 15, 2003).

The ALJ noted that the first time that the Government cited to this section was in its Supplemental Prehearing Statement. RD, at 101 n.49, 102 n.50 (citing ALJX 22, at 4). He determined that this regulation was never mentioned during the hearing, and ''[f]urthermore, the Government expert did not rely on N.J. Admin. Code § 13:35.71A in reaching his conclusion that the Respondent's prescriptions to A.D. were issued beneath the standard of care in New Jersey.'' RD, at 101, n.49 (citing tr. 272, 674–77). He therefore concluded that Respondent ''was not put on notice that any of her prescriptions violated'' this provision. *Id.* The ALJ further noted that his recommended sanction would not have changed had he considered those provisions. RD, at 102 n.50. I disagree that N.J. Admin. Code § 13:35.71A was not sufficiently noticed or litigated during the hearing.

The Government's Supplemental Prehearing Statement used bold type to emphasize changes to the testimony of Dr. Kaufman, stating, ''Dr. Kaufman will also testify that the New Jersey standard of care is also governed by N.J. Stat. Section 13.35–7.1A and 13:35–7.6.'' Govt Supp Prehearing, at 4, 5. On August 20, 2018, Respondent filed a motion objecting to the Government's Supplemental Prehearing Statement, and made a correction to the Government's citation of the regulation, stating, ''Among other things, Dr. Kaufman's testimony has been changed to allege respondent's violation of New Jersey regulations—improperly identified as statutes—in the revised proposed testimony.'' Respondent's Pre-Trial Motions, at 9.

During the hearing, the Government's attorney asked Dr. Kaufman if the requirement for a physical exam had recently changed in New Jersey and Dr. Kaufman said that it had not. Tr. 271–72. The Government's attorney then asked if, in 2015, someone would be required to do a physical exam to which the witness responded, ''[W]ithout

[10] Respondent specifically highlighted this fact in stating, ''The ALJ also ignored the fact that Dr. Gutheil was not qualified to, and could not, testify to the standard of care.'' Respondent's Exceptions, at 16 (citing tr. 1158–1159).

reviewing the statute [11] again, I believe so.'' *Id.* The Government's attorney clarified by asking if the ''standard of care require[d] a physical exam, regardless of what the statute says,'' to which Dr. Kaufman answered, ''Yes.'' *Id.* Later, Dr. Kaufman testified that the regulation requires that a physical exam must be conducted, and in response, the Respondent's attorney specifically cited to this regulation to pose an argument that the regulation contained exceptions to the physical examination requirement and he presented copies of the regulation to the ALJ and Dr. Kaufman. *Id.* at 399–405.

Ultimately, the ALJ agreed with the Government's allegations regarding Respondent's failure to conduct a physical examination of the UC before prescribing controlled substances, because he found that Respondent's actions were beneath the applicable standard of care and outside the usual course of the professional practice in New Jersey. RD, at 38. Even though the ALJ recommended dismissing the allegations of a regulatory violation, he did not change his overall conclusion that the lack of a physical examination violated the applicable standard of care in New Jersey. I agree with the Government, and the Respondent, that the Government adequately noticed the regulatory and statutory violations, and at the very least, this regulation was clearly litigated by consent during the hearing, as exemplified by the Respondent's arguments during the hearing and in Respondent's Exceptions. *See Farmacia Yani,* 80 FR 29,053, 29,059 (2015). Therefore, I will consider the allegations regarding New Jersey Administrative Code § 13:35–7.1A.

2. New Jersey Administrative Code § 13:35–7.6

The Government also cited to New Jersey Administrative Code Section 13:35–7.6 in its Supplemental Prehearing Statement, which sets forth numerous requirements for practitioners prescribing controlled substances, including entering a pain management plan by the third visit and monitoring compliance. There are two affirmative obligations in this Section of the regulations that are applicable to this record—''[w]hen controlled dangerous substances are continuously prescribed for management of chronic pain'' [12] (defined as pain continuing for three months), the practitioner shall ''assess the patient prior to issuing each prescription to determine whether the patient is experiencing problems associated with physical and psychological dependence, and document the results of that assessment'' and ''monitor compliance with the pain management agreement . . . and discuss with the patient any breaches that reflect that the patient is not taking the drugs prescribed or is taking drugs, illicit or prescribed by other practitioners or prescribers, and document within the patient record the plan after that discussion.'' N.J. Admin. Code §§ 13:35–7.6(f)(2), (f)(5) (West 2020).[13] Respondent testified that all of the patients whose treatments were the subject of this action signed a pain management agreement with her. Tr. 948; *see, e.g.,* GX 29, at 4 (pain management agreement with the UC). She further testified that she would use her ''clinical judgment'' to determine whether a patient's conduct broke her agreement. Tr. 1007–08. One of the pain management agreements for J.C. stated, ''I will use my medicine at a rate no greater than the prescribed rate and that use of my medicine at a greater rate will result in my being without medication for a period of time.'' [14] GX 130, at 12. The plain language of the regulation requires that a practitioner discuss with the patient ''breaches that reflect that the patient is not taking the drugs as prescribed,'' which would include inconsistent urine screens that clearly demonstrate that the patient has not been following the prescription. N.J. Admin. Code § 13:35–7.6(f)(5) (West 2020); *see infra* Section III(A)(1)(b)(ii) for further discussion.

The ALJ concluded that despite discussion of Respondent's pain agreements in the testimony,[15] the Government had failed to adequately notice ''that the Respondent failed to enter into such agreements or conduct urine drug screens.'' [16] RD, at 105 n.59. The Government argued not, as the ALJ contended, that she failed to enter into agreements, but that the regulation required Respondent to discuss breaches of the pain management agreement and document within the patient record the plan after the discussion, and alleged that Respondent issued eleven prescriptions for controlled substances in violation of this regulation. Government's Posthearing Brief (hereinafter, Govt Posthearing), at 17. The Respondent posed arguments both in her testimony and in her Posthearing Brief regarding her monitoring of the patients for dependence and her discussion of the inconsistent urine screens and how her documentation complied with the regulation. *See, e.g.,* tr. 1024–1025; Resp Posthearing, at 18–20, 23. Respondent's arguments before the hearing,[17] during the hearing, and after the hearing, demonstrate that she was on notice of the alleged violation of the New Jersey regulation; therefore, I disagree with the ALJ that this allegation was not adequately noticed, and I will consider the alleged violations of this regulation after its effective date of March 1, 2017.

Further, at the very least, this regulation fully supports the testimony of Dr. Kaufman and discredits the testimony of Dr. Epstein regarding whether the applicable standard of care in New Jersey requires documentation of inconsistent urine screens as further explained below in Section II(E)(1) and (3).

3. New Jersey Statute 24:21–15.2

The OSC alleged that Respondent did not ''comply with New Jersey Stat. [ ]§ 24:21–15.2 [18] (requirements for

[11] Dr. Kaufman used the word ''statute'' here, but he appears to be confusing the regulation and statute.

[12] '' 'Chronic pain' means pain that persists for three or more consecutive months and after reasonable medical efforts have been made to relieve the pain or its cause, it continues, either continuously or episodically.'' N.J. Admin. Code 13:35–7.6(a) (West 2020). Due to the fact that the patients in this case were prescribed opioids for more than three months prior to this regulation, I find that they fall under this definition.

[13] The requirement related to the assessing, monitoring and documenting of compliance in N.J. Admin. Code § 13:35–7.6(f)(2) and (5) became effective on March 1, 2017, through an Emergency Rule. 2017 NJ REG TEXT 452254 (NS) (Emergency Rule). The regulation became permanent on June 5, 2017. 2017 NJ REG TEXT 452254 (NS) (Rule Adoptions).

[14] The record reflects that Respondent had two pain management agreements. The record contains one pain management agreement that makes no reference to taking the medicine as prescribed, but the other states that ''I will not attempt to obtain any controlled medicines, including opioid pain medicines, controlled stimulants, or anti-anxiety medications from any other doctor.'' GX 130, at 12; *cf* GX 130, at 2 (different pain management agreements with J.C.). To the extent that the pain management agreements do not address the required portions of the regulation, they appear to be inadequate. Regardless of the content of the actual pain management agreements, the regulation is clear about what would constitute a breach: not taking the medication as prescribed and taking drugs not prescribed or prescribed by other practitioners. I am basing my Decision and Order on the regulatory requirements as opposed to Respondent's agreements.

[15] *See, e.g.,* tr. 947–950.

[16] The ALJ seemed to be confused between this regulation and New Jersey Stat. § 24:21–15.2, but substantively, as further explained herein in *infra* Section III(A)(1)(b)., the regulation implements the statute; therefore, they are very similar. *See* RD, at 105 n.59. I also disagree that the Respondent was not on notice of the allegations regarding pain management agreements, because they are identical in scope to the requirement to document the resolution of evidence that the patient was not taking the medication as prescribed or was taking controlled substances that were not prescribed.

[17] *See* Respondent's Pre-Trial Motions, at 9 n.1.

[18] It is noted that the OSC alleged a violation of this statute for the prescriptions written to the UC

opioid and Schedule II controlled substances prescriptions).'' [19] ALJX 1 (OSC) at 2. The OSC alleged that New Jersey Stat. § 24:21–15.2:

> requires, among other things, that a physical exam take place prior to the issuance of a Schedule II controlled substance prescription or opioid prescription; that a doctor prescribing opioids enters [*sic*] into a pain management agreement with patients; and that patients receiving opioids be monitored for compliance with the pain management agreement through various measures such as urine drug screens.

OSC at 2.

During cross examination, Respondent's attorney asked Dr. Kaufman about the statutes to which he was testifying and Dr. Kaufman replied that he didn't know them by number, but he knew them in substance. Tr. 297–298. He testified that the substance was:

> that you must do a full history, in general, an appropriate physical exam. You must also check the prescription monitoring programs, and then issue a prescription. On subsequent visits, you need to make an assessment of the prescribed medicine. Is it working? Is it not working? You need to, again, do a physical exam, and then come up with a plan to then say do we continue the medication, or do we not continue it? That's the general substance of that.

Id. at 299–300.

Later, on cross examination, the ALJ overruled Government's objection when Respondent's attorney required Dr. Kaufman to read a statute,[20] holding ''[h]e has testified based on his understanding of the statutes. It's appropriate to allow Counsel to ask him, looking at the statutes, based on your reading of the statutes, do you think you've interpreted it correctly.'' *Id.* at 303.

The Government and Respondent both presented arguments about N.J. Stat. § 24:21–15.2 in prehearing and posthearing filings, and therefore, I find that it was adequately noticed and will consider it below for prescriptions issued after its effective date. *See, e.g.,* Govt Supp Prehearing, at 4; Resp Supp Prehearing, at 2.

(all of which were issued prior to its effective date and which were the only allegations on the record regarding a lack of physical examination); therefore, the physical examination portions of the statute are not directly relevant to the findings herein.

[19] The OSC also alleged violations of N.J. Stat. § 45:9–22.19 (requirements for additional schedule II controlled substances prescriptions), but the Government did not offer further argument related to that provision—apparently abandoning it. Thus, I am not considering it.

[20] Although not explicit in the transcript, the contextual clues demonstrate that the ''statute'' was New Jersey Stat. § 24:21–15.2 (effective May 16, 2017). Tr. 302–303.

E. The Applicable Standard of Care in New Jersey

1. Expert Testimony

In accepting Dr. Epstein as an expert witness despite his lack of specific expertise in the New Jersey standard of care, the ALJ cited *Jacobo Dreszer, M.D.,* in which my predecessor stated that, due to an ''expert's academic and professional credentials, and the expert's testimony that he reviewed the state's regulations [21] governing the standards of prescribing controlled substances, the expert was 'clearly qualified to provide expert testimony.' '' RD, at 12 (citing *Jacobo Dreszer, M.D.,* 76 FR 19 386, 19 387 (2011)). The ALJ opined that it was significant that Dr. Epstein testified that there is a nationwide standard of care with respect to prescribing opioids, which, he testified, ''establishes the floor.'' RD, at 13; tr. 722, 725. The ALJ noted that while Agency decisions exist to tailor analysis of medical practice to state standards, DEA ''has also accepted the propriety of analyzing the usual course of professional practice with reference to generally recognized and accepted medical practices that exist on a national level.'' RD, at 16 (citing *Mirielle Lalanne, M.D.,* 78 FR 47 750, 47 759 (2013)). He found, however, that in this case neither Dr. Kaufman nor Dr. Epstein based their opinions on New Jersey law or regulations, and that ''absent such controlling state laws or regulations . . . it is appropriate to focus upon whether the physician prescribes medicine in accordance with a standard of medical practice generally recognized and accepted in the United States.' '' RD, at 16 n.2 (citations omitted). As noted in the previous section, Dr. Kaufman did acknowledge the substance of New Jersey law, and although he did not quote those authorities directly, they were part of his understanding of the applicable New Jersey standard of care and support the standard to which he testified. *See, e.g.,* tr. 272.

I do not disagree with the ALJ's determination regarding Dr. Epstein's general credibility or his admission as an expert; however, it is important to emphasize that the OSC alleges that Respondent prescribed ''outside the usual course of practice and beneath the standard of care in New Jersey.'' OSC, at 2–5; *see* RD, at 12; tr. 721–722. The question in this case is, regardless of the rationality, credibility, and impressive credentials of an expert in a national standard of care, whether such an expert's view can outweigh expert testimony concerning the applicable New Jersey standard of care, which in several aspects has been codified in state law and regulation.

Dr. Epstein testified that New Jersey laws and regulations ''can further limit the prescribing,'' and agreed with the Government attorney that ''Federal law [22] sets maybe a floor but the community can have higher standards, but the community can't have lower standards.'' Tr. 725. Dr. Epstein then asserted that the standard of care is ''dictated by communities rather than by states,'' and that the New York metropolitan area is one community, including parts of New Jersey, and suburban practitioners have different standards of care than those in urban areas. RD, at 13; tr. 704, 711, 715. When asked if the standard of care in New York is different from New Jersey, he stated, ''[i]n my opinion, they are the same. The Board of Medicine in New Jersey may feel they're different.'' Tr. 713.

In this case, New Jersey has enacted laws and regulations, which, as Dr. Epstein predicted, have put in place ''higher standards'' than those upon which Dr. Epstein relies. *Id.* at 725. To the extent that Dr. Epstein discussed a baseline national standard of care, the laws and regulations of New Jersey and the direct testimony of a New Jersey practitioner directly contradict Dr. Epstein's depiction of the applicable standard of care. Although I recognize that some of the New Jersey laws and regulations in question were enacted after some of Respondent's alleged violations, because those authorities are consistent with the standard of care described by Dr. Kaufman, I give Dr. Kaufman's testimony more credibility than Dr. Epstein's.[23]

[21] It is noted that although Dr. Epstein stated that he read recent statutes, he stated that the standard of care ''doesn't include the statute'' and he appeared to be unfamiliar with the New Jersey laws. Tr. 704, 708–709, 711.

[22] In discussing federal law, Dr. Epstein seemed to be referring to the Center for Disease Control Guidelines that he referenced earlier in his testimony. Tr. 723–724. This demonstrates Dr. Epstein's general misunderstanding about the weight of applicable laws and guidance and the manner in which they affect the applicable standard of care in New Jersey.

[23] Additionally, I note that it would defy logic to find Dr. Epstein more credible on matters of standard of care for the prescriptions that occurred after the effective date of these New Jersey laws, as the standard that he describes would be in direct violation of state law. *See* N.J. Admin. Code § 13:35–7.6(f)(5) (West 2020) (requiring documentation of breaches of the pain management agreement that demonstrate that the patient is not taking the medication as prescribed); *but see* tr. 1629–41 (Dr. Epstein testifying that documentation is a best practice, not the standard of care in New Jersey).

2. Physical Examination

The ALJ found, and I agree, that, before prescribing a controlled substance, the applicable standard of care in New Jersey ''requires a full medical history, a targeted physical examination based on the patient's complaint, review of relevant documents, and checking the PMP.'' RD, at 38 (citing tr. 174, 180, 271, 1442). Dr. Kaufman credibly testified that the applicable New Jersey standard of care requires a physical examination [24] of a patient before prescribing a Schedule II controlled substance, including on return visits, and that observing a patient would not satisfy the applicable standard of care. RD, at 9 (citing tr. 181, 398, 462). He also testified that a component of a physical exam is ''[c]ould you please move while I watch you and observe you and measure how much you can move it, that's part of a physical exam,'' but that undirected movement is an ''observation [ ] that's not a physical examination.'' Tr. 415, 430. He testified that ''[e]ach time before prescribing a controlled substance, one needs to examine to see if the medication that you're giving is helping. Is it efficacious? Is the examination changed? Do you want to then continue therapy? '' *Id.* at 398.

Dr. Epstein stated that the standard of care requires a diagnosis obtained by ''a thorough history and then a physical that's directed, which can vary in scope [25] and [ ] enough at least to get the right diagnosis, and to get a working diagnosis, and to do whatever diagnostic tests that you need to do if you need to do them, and to provide a diagnosis, provide a plan, discuss risks, and then implement the plan, and then to follow-up on the plan. . . .'' Tr. 1442. As further evidence of the applicable New Jersey standard of care, the Government cited to New Jersey Administrative Code § 13:35–7.1A, which was in effect at the time of the prescriptions to the UC, and requires in relevant part that practitioners shall not dispense drugs or issue prescriptions ''without first having conducted an examination, which shall be appropriately documented in the patient record'' and part of that examination requires the practitioner to ''perform an appropriate history and physical examination.'' N.J. Admin. Code § 13:35–7.1A(a) and (a)(1) (West 2020).

As further explained below, I find that the applicable standard of care in New Jersey requires a physical examination, including a directed physical examination of the area of complaint, and that observation without directed movement, is not adequate under the applicable standard of care.[26]

3. Urine Screens Inconsistent With Prescribed Medication

Dr. Kaufman testified that a urine screen [27] that is negative for the controlled substance that the practitioner has prescribed is an inconsistent urine screen, and further that, when a patient's urine screen is inconsistent, the applicable standard of care in New Jersey requires a practitioner to ''have a discussion with the patient and to say, I gave you X amount of medication to last you from one visit to the other. And I'm not seeing anything, not the parent compound, which you would see if you had taken it that day, nor the breakdown products that you would see anywhere from three to four days later, why did you finish these sooner than how I prescribed them?'' Tr. 200. Further, he testified that the applicable standard of care requires the practitioner to document that conversation in the patient record ''for the record[] to show that you've had this discussion,'' because ''within the State of New Jersey, each time the patient comes in, you're supposed to assess the patient, to make sure that, A, that they're taking it. B, that it is efficacious, are there any side effects? And then, make a justification as to continuation of therapy.'' *Id.* at 201–202.

Dr. Epstein testified at several points that a urine screen that comes back negative for the controlled substance that was prescribed has two possible answers: ''the patient used the medication, finished the medication;'' or that ''they're diverting it, that they're not using it at all.'' *Id.* at 1501–02. He testified that the urine screens of diverters would be positive for opioids, because Respondent was conducting regular and predictable urine tests, so diverters would know to ''take the oxycodone for three or four days so that they develop a blood level and the metabolites'' to avoid detection, because ''[t]hey're not stupid. They're making a lot of money at this.'' *Id.* at 1502. Later, Dr. Epstein stated, ''There's zero way to defend against patients selling half or a third of their medication'' and that because of the low dose ''if it was positive on every urine tox, [he] would actually kind of wonder about that . . . how did they have enough to take this all the time.'' *Id.* at 1566. Dr. Epstein later testified that he had not ''thought about the one that [the Government] came up with, which is they're putting them—they're—they're hoarding which, honestly, I hadn't really thought of as a possibility.'' *Id.* at 1584.[28] He also

[24] Respondent insinuated that Dr. Kaufman testified that ''[i]f a physician knows the reasons for a patient's pain, there isn't necessarily a need to actually palpate the patient (Kaufman [304]).'' Resp Posthearing, at 11. The transcript does not support this statement. Dr. Kaufman testified, ''How could you never need a physical exam when someone's complaining of pain in a body part'' and explained that the only time the standard of care would not require a physical examination is if ''a patient's coming in to me with terminal cancer pain, I'm not going to subject them to what could be a very painful examination to know that they have cancer in bones or other organs, which we're now trying to alleviate their suffering.'' Tr. 304.

[25] Respondent argued, among other things, that the variance in scope that Dr. Epstein describes supports her argument that a physical exam is only necessary as appropriate in the physician's sound medical opinion. Resp Exceptions, at 9. In making his initial assessment, Dr. Epstein relied on Respondent's records for the UC that had misleadingly indicated that a physical exam was performed, because Respondent's system auto-populated the template. Tr. 176; GX 29; tr. 827, 904, 914. I note that Dr. Epstein did not state that a physical exam required palpation, but his statements about the requirements of a physical exam were minimal and did not elucidate the appropriate contents of a physical examination, because he had assumed that the physical exam had occurred. Further, Dr. Epstein's testimony undermines Repondent's argument that an MRI is adequate in lieu of a physical examination, because he sequences the physical examination first and differentiates between the physical and the ''diagnostic tests that you need to do if you need to do them.'' Tr. 1442. However, due to the limited nature of Dr. Epstein's testimony on this issue, Dr. Kaufman's testimony regarding what constitutes a physical examination is the only expert testimony on the record that addresses the contents of the physical examination, and I fully credit his testimony on this issue.

[26] Respondent's arguments related to the extent of the physical exam are further discussed below. *See infra* Section II(F)(1) and III(A)(1)(b)(i).

[27] The ALJ found that ''[a] doctor's first assumption when reviewing an abnormal urine screen for a patient is that the test is wrong. Laboratories make mistakes all the time.'' RD, at 42 (citing tr. 1492). Respondent noted that the ALJ seemingly ignored this finding of fact when sustaining the allegations. Resp Exceptions, at 27. I do not find this finding of fact to be inconsistent with Dr. Kaufman's testimony about the applicable New Jersey standard of care's requirement to document inconsistent urine screens as described herein. Without such documentation, for example, there is no way to know how an incorrect laboratory result was resolved or why a practitioner believed it to be incorrect.

[28] Reading the transcripts, I find it difficult to agree with the ALJ's assessment of Dr. Epstein's testimony when he stated that it was ''far more cogent and convincing than was Dr. Kaufman's'' on the issue of counseling and documentation. RD, at 116. The ALJ seemed concerned with ''why the standard of care required documentation of counseling about an inconsistent urine screen.'' *Id.* at n.64. The policy rationale for the requirements can be useful in understanding the applicable standard of care, but it should not be used to confuse the evaluation of what the applicable standard of care actually requires, particularly regarding bright line issues such as the documentation of counseling. Additionally, as shown here, Dr. Epstein's rationale about diverting patients who are purposefully taking the medication before the test to not raise suspicion at his own admission did not consider patients who might be hoarding or patients who are addicted and are taking too much of the medication at once. Tr.

testified that the applicable standard of care on an inconsistent urine screen is based on ''being judicial'' and asking whether the patient has a ''good excuse.'' *Id.* at 1504. He testified later that the applicable standard of care for a patient who has doubled the medication is to say ''that's dangerous, you should not do that, why did you do that. Said my pain was completely out of control. You—you counsel them. You tell them not to do that . . . .'' *Id.* at 1575. His testimony does appear to agree with Dr. Kaufman that inconsistent screens require counseling. In contrast with Dr. Kaufman, Dr. Epstein testified that documenting the conversation after inconsistent urine screens is a ''best practice,'' as opposed to the standard of care, and that ''[i]t should be done, [b]ut it's not technically standard of care.'' *Id.* at 1629–41; *id.* at 1630–31.

Much of Dr. Epstein's testimony was aimed at justifying why addressing an inconsistent urine screen is not, in his view, critical in preventing the diversion of opioids, but the issue in this case is whether the applicable standard of care in the State of New Jersey requires a practitioner to address an inconsistent urine screen, including with counseling, and whether and to what extent the practitioner must document an inconsistent urine screen.

Support for the credibility of Dr. Kaufman's testimony is that, beginning on March 1, 2017, a New Jersey regulation required that a physician prescribing controlled substances for the treatment of chronic pain enter into a pain management agreement with the patient and monitor the patient's compliance with that agreement to include documentation of any breaches that indicated that the patient was not taking the medication as prescribed. *See* N.J. Admin. Code § 13:35–7.6(f)(5) (West 2020). I find that the existence of this regulation fully supports Dr. Kaufman's testimony that, after an inconsistent urine screen, the applicable standard of care in New Jersey requires the practitioner to counsel and document the resolution of the inconsistent screen, and after March 1, 2017, this practice was also required by law. Even though the regulation was not in effect for the entirety of the period of violations alleged in the OSC, its existence undermines Dr. Epstein's testimony regarding the applicable standard of care for inconsistent urine screens in this case, some of which occurred after the regulation became New Jersey law. This regulation had been in existence for a year and a half prior to Dr. Epstein's testimony and the language of the regulation clearly requires documentation not just as a ''best practice.'' Therefore, I credit Dr. Kaufman's testimony regarding inconsistent urine screens over Dr. Epstein's and find that documentation of the resolution of the inconsistent urine screens is required under the applicable standard of care in New Jersey.

(a) Whether Counseling Regarding the Inconsistent Urine Screens Occurred

The Respondent dedicated substantial time in proffering that she always counseled her patients regarding negative urine screens through her own testimony and that of her patient J.C. *See e.g.,* Tr. 805, 813, 853, 935, 1343–45. The ALJ did ''not find that the Government met its burden of proving that [Respondent] did not counsel her patients, rather the weight of the evidence establishes that [Respondent] routinely counseled her patients about the results of their urine screens.'' RD, at 115. In coming to this conclusion, the ALJ credited the video recording and transcript of Respondent's fourth visit with the UC, in which she said, ''your urine last month did not show any medicine,'' and when the UC said that it wasn't ''lasting [her],'' Respondent asked how many she needed in one day and increased her dosage. GX 15, at 5; RD, at 115, 149. The Government argued that the ALJ erred in determining that this statement constituted counseling and that he ''improperly substituted his medical opinion for that of the medical experts,'' because the Government's expert provided testimony that the applicable standard of care requires more than just identifying an issue. Govt Exceptions, at 2–3.[29] When asked about these statements that occurred during the UC's fourth visit, Dr. Kaufman credibly testified that Respondent ''rightly questioned why a urine screen that they did came back negative.'' Tr. at 185. However, Dr. Kaufman also testified that this interaction did not meet the applicable standard of care for counseling a patient with an inconsistent urine screen, because he stated, ''[I]f the patient is telling me, well, it's not lasting, and if the patient is saying that the pain is getting worse, I need to investigate why is the pain getting worse, not just say, well, here's another prescription, you need to make it last.'' *Id.* at 187–188.

Respondent testified that when a urine test comes back clean, she would state, ''Last month's urine was—didn't show any of your—any medication, why is that? And, when was the last time you took your medication? How often are you taking it? Are you taking it every—like I wrote it?'' *Id.* at 978. She further testified that she would ask, ''How are you taking it? Like I'm prescribing it? Did you take more? Do you have any left? Did you go to the emergency room for any reason?'' *Id.* at 979. Additionally, she argued that she would tell her patients that if they continued to have inconsistent urines, she would stop prescribing them opiates. Resp Posthearing, at 35 (citing J.C.'s testimony at 1343, 1345). The interaction with the UC demonstrates that she asked one or two of the questions that she said she always asks, but none of the follow up questions or the potential consequences. Her videotaped questioning of the UC regarding her inconsistent urine did not even meet what she had described as her own practices after an inconsistent urine screen.

In the case of patient records, it is impossible to know for certain one way or the other whether the counseling occurred if it was not documented. The evidence in the record shows that the UC was partially counseled once for her inconsistent urine screen, but the Government presented evidence that that counseling did not meet the applicable standard of care, nor was it documented. The ALJ found and I agree that the Respondent and her patient J.C. had dubious credibility, but the ALJ still deferred to them both that the counseling occurred. The windows through which we can clearly see what likely occurred are the recorded visits between Respondent and the UC, where the Government has demonstrated that the Respondent did not adequately counsel and that her recordkeeping was unreliable. *See, e.g.,* GX 18, at 2 (counseling not to smoke noted in the patient file but did not take place according to video recording and transcript of visit); GX 18, 19, 21, 23, 25 (physical examination noted in the patient file did not take place according to the video recording and transcript of the visit). Therefore, the record shows that Respondent did not always counsel her patients as she repeatedly testified. *See* Tr. 805, 813, 853, 935. Despite the record's demonstration that Respondent did not counsel her patients as she claimed, this deficiency in Respondent's practice is not determinative, because even if appropriate counseling occurred,

1584. I did not find Dr. Epstein's testimony on this matter to be cogent or convincing.

[29] This particular interaction between Respondent and the UC was not included in the Government's allegations and therefore, it is only being considered as evidence to show whether Respondent regularly counseled her patients.

Respondent did not document required counseling in most instances, the exceptions being a few alcohol-related instances.[30]

(b) Timing of an Inconsistent Urine Screen

Establishing that the applicable standard of care in New Jersey requires a practitioner to address and document an inconsistent urine screen, the Government put forward evidence attempting to establish a timeframe for when the patient's negative urine screen would be considered inconsistent and thus the lack of documentation of counseling would implicate a violation of prescribing beneath the applicable standard of care. Dr. Kaufman testified that a negative urine screen would be consistent if the patient came back thirty-five days after being issued a thirty-day prescription for oxycodone, because the oxycodone would likely no longer be in the patient's system. Tr. 206–07; 494. Dr. Kaufman further testified that if a prescription for thirty days was filled within thirty-three days of the negative urine screen, it would be inconsistent. *Id.* at 208; 497 (''I would still expect to see that . . . 33 days. 34 days, probably not.''); *see also id.* at 652 (confirming that at thirty-three days, Dr. Kaufman would expect to see metabolites for opioids). The ALJ found that Dr. Epstein testified that some individuals metabolize opioids in one-to-two days. RD, at 122 (citing tr. 1501–02). Dr. Epstein's testimony was more focused on the reasons to be concerned about the negative urine screen than on setting a specific timeframe, but he did state that ''if it's more than about 33 days since it was filled, then at that point, I'm not concerned.'' *Id.* at 1501. When pressed, Dr. Epstein testified that ''the appropriate measuring stick'' for negative urine was the date the prescription was filled but was ''not a black and white.'' *Id.* at 1530. Later, Dr. Epstein testified that he would not be surprised if a patient's urine was clean after a prescription for sixty pills, with a maximum of two per day on day thirty, because ''patients are going to sometimes hurt and sometimes not'' and ''my patients will have a week or two that they don't use any meds.'' *Id.* at 1552. He further said that ''a red flag is someone that never misses,'' but when asked by the ALJ if what he was stating was that a patient taking medication as prescribed would be concerning, Dr. Epstein said that was not his ''intent.'' *Id.* at 1552, 1553. He stated that he cannot write a prescription for ''p.r.n.'' six times a day and give sixty pills, because the pharmacy will flag it as not enough pills, but that he wants the pills to ''average out to no more than twice a day by the end of the month.'' *Id.* at 1554–55. Despite Dr. Epstein's testimony about what would ''concern'' [31] him regarding negative urine screens, he generally testified that when there is ''an inconsistent UTOX, your first response is to reevaluate it and to—and to—combine that information with what else you know about the patient and with what their status is, why you're giving the drug, how they're responding to it, and—and—and whether everything else about them seems reasonable.'' *Id.* at 1590–91.

The ALJ found that the Government ''has the burden of proof to establish when a urine screen is inconsistent'' and that ''[t]he Government chose to meet its burden by offering evidence of an estimate of when the results of a urine screen would be inconsistent.'' RD, at 122. I agree with the ALJ's statement, but I do not believe that the record supports his finding that the date that was established is ''up to and including 32 days prior to providing a urine sample.'' [32] *Id.* Both Dr. Epstein and Dr. Kaufman testified that if it is *more than* about thirty-three days, they would not be concerned. Tr. 1501 (Epstein); *id.* at 652 (Kaufman).[33] Therefore, I find that the record in this case has established that a urine screen becomes inconsistent with a thirty-day prescription when it is negative for the prescribed controlled substances more than thirty-three days after the fill date.[34]

(c) Level of Documentation Regarding Inconsistent Urine Screens

The Respondent also posed arguments regarding the level of documentation that is required when there is an inconsistent screen. Respondent argued that the automatic counseling note that she included in combination with the maintenance of the results of the urine tests in the patient's record constitute adequate documentation of the counseling and the fact that the screen was addressed. *Id.* at 1026–1027. She further argued that her documentation system, eClinical, would not permit her to type information into the plan section, but she admitted that she could have typed information into other sections. *Id.* at 914–15; RD, at 45. The regulations require that when there are any breaches of the pain management agreement that demonstrate that the patient is not taking the medication as prescribed, the practitioner must ''document within the patient record the plan after that discussion.'' N.J. Admin. Code § 13:35–7.6(f)(5) (West 2020). It is clear from a plain reading of the regulation that the requirement for documentation is greater than just recording the urine results, and that there needs to be a documented plan as well. *See infra* III(A)(1)(b)(ii) or further discussion. The regulation further bolsters Dr. Kaufman's testimony that Respondent's counseling notes that she selected to autopopulate in eClinical were not adequate under the applicable standard of care. Specifically, he testified regarding the counseling notes that ''it was not counseled—I don't see a statement in here, which I've stated before, that there was the medication need to be taken as directed, that you need to not double up on the

[30] Dr. Kaufman testified that if counseling is not documented, it did not happen. RD, at 115 (citing tr. 485–86, 632). The ALJ stated that ''that premise . . . does not exist in a vacuum.'' Although I do not disagree with the ALJ that the distinction can be meaningful, the effect of a finding that Respondent *did* counsel her patients for the majority of noticed instances only would mitigate the overall egregiousness of the prescriptions that violated the applicable standard of care and, as explained in *infra* Sections III and IV, I find that the violations solely based on the lack of required patient file documentation are egregious enough to call for revocation, particularly in light of the fact that the Respondent did not accept responsibility.

[31] Throughout Dr. Epstein testified about when a red flag might be a ''concern,'' but it is unclear what the result of the concern would be. In some cases he appears to be discussing discharge of the patient and sometimes he says ''maybe I'm concerned and concerned enough to—to take a good look at it'' and ''we would not stop prescribing.'' Tr. 1559. It is difficult to distinguish in his testimony when a practitioner's concern would require counseling, and it is another reason why I find Dr. Kaufman more credible on this matter, because he was clearer about what the concern is and what the concern requires under the applicable standard of care.

[32] Even if I did agree with the ALJ, only two prescriptions are affected by my finding (one to Patient J.C. and one to Patient A.P. (but which I still find was issued beneath the applicable standard of care due to lack of counseling on a positive alcohol test)) and if I were to reverse my finding on the one prescription to J.C., it would in no way affect my overall recommendation of sanction in this case.

[33] Respondent characterizes Dr. Epstein's testimony as a screen taken thity-three days after a thirty-day prescription was filled, but he actually stated that ''more than about 33 days,'' which is also consistent with his one-to-three day estimate. *See* Respondent's Posthearing, at 32.

[34] I find this fact reluctantly and emphasize that I find it only in the context of the evidence presented in this case, because the Government presented its evidence using a bright line rule regarding when to consider a urine screen as triggering the requirement for documentation. When a patient's urine is negative for opioids, even when the amount of the prescription should have reasonably been out of the patient's system, it would still make logical sense that a practitioner should address why the patient did not need the medication, did not go into withdrawal etc. Although bright line rules can be useful, Dr. Kaufman testified that the purpose of the monitoring and documentation requirement is to ensure that the patient is taking the medication as prescribed and is not diverting or abusing the medication, and to determine whether continuation of the prescribing is warranted and ''to make a justification as to continuation of therapy.'' Tr. 202.

medications, because that's going to put you at risk for other issues. I don't see that statement here.'' Tr. 612; *see also id* at 610. Dr. Kaufman clarified that the eClinical automatic entry that appeared in many of Respondent's records and stated ''take your medication regularly'' means only ''you take it on a regular basis.'' *Id.* at 612. These notations do not indicate any plan to address the failure of the patient to take the medication as prescribed, and therefore, I find that these notations are inadequate documentation under the applicable standard of care in New Jersey.[35] I agree with the ALJ's ultimate finding that the applicable standard of care in New Jersey requires ''a practitioner to document the cause and resolution of inconsistent urine drug screens, as well as the practitioner's discussion with the patient about the urine drug screens.'' RD, at 117.

(d) Whether a Patient Must Be Dismissed for Inconsistent Urine

In this case, I find that Dr. Kaufman and Dr. Epstein were generally in agreement that the matter of what a practitioner is required to do when the urine screen is inconsistent is not ''black or white,'' and where the toxicology screen is negative, the issue is not necessarily whether the practitioner stops prescribing the controlled substance. *Id.* at 1609. Dr. Epstein testified that ''[t]he standard of care is to counsel them. The standard of care is to reestablish the norm and to determine if you need to change the dosage, change the treatment, change the medication, do any of those things that you need to do to get them under control if they're not already.'' *Id.* at 1585. Dr. Kaufman testified that a patient who admitted that he or she ''doubled up on a few days during the month'' would not disqualify the patient from getting another prescription, but would instead instigate questions from the practitioner to ''elucidate why this increase in pain occurred and treat it appropriately.'' *Id.* at 643. Overall, I find that the substantial evidence on the record demonstrates that the applicable standard of care in New Jersey, as verified by the regulation, requires that the inconsistent urine screen be addressed, counseled, and documented. *See* N.J. Admin. Code § 13:35–7.6(f)(5) (West 2020).

(e) Positive Urine Screen for Non-Prescribed Controlled Substances

Dr. Kaufman credibly testified that when the patient tests positive for a non-prescribed controlled substance, the applicable standard of care in New Jersey requires the practitioner to address the urine test with the patient and ''to document their conversation in the medical record.'' [36] Tr. 241, 244 (he would expect to see specific discussion of the other controlled substance in the medical record on the subsequent visit). This concept is further supported by the New Jersey regulation requiring a practitioner to address breaches of pain management agreements and document the plan. *See* N.J. Admin. Code § 13:35–7.6(f)(5) (West 2020). Dr. Epstein testified that when the PMP shows prescriptions for opioids about which he was not aware, it would be a concern, but for certain types of opioids ''then that's okay as long as I know that's happening.'' *Id.* at 1594. Regarding fentanyl, he testified that upon a second test [37] within a limited timeframe demonstrating a non-prescribed controlled substance, ''you would speak to the patient, you would try to figure out if there was a reason for it, you know, if there was some sort of—you know, they had had other tests. . . .'' *Id.* at 1604. Although Dr. Epstein did not explicitly testify that there needed to be a conversation with the patient about the screen, his testimony and findings imply that he would need to know what's ''happening.'' *Id.* at 1594. He also stated that ''[he has] to always explore'' what is going on. Tr. 1604. The primary difference between the two experts was that Dr. Kaufman testified that the applicable standard of care required the practitioner to document the resolution of the positive screen and Dr. Epstein did not. Dr. Epstein testified, ''There's actually no regulation anywhere that I know of in any state that says what needs to be, exactly says how the medical record, how much you have to put in.'' (Tr. 1630–1631). He also said that documentation is a ''best practice. It's really not standard of care. Because it's not care. Okay. It's not care. It's best practice. And it should be done, you know. It should be done.'' Tr. 1631. New Jersey's regulations contradict Dr. Epstein's testimony.[38] The regulations require that practitioner shall ''assess the patient prior to issuing each prescription to determine whether the patient is experiencing problems associated with physical and psychological dependence, and document the results of that assessment'' and ''monitor compliance with the pain management agreement . . . and discuss with the patient any breaches that reflect that the patient is not taking the drugs prescribed or is taking drugs, illicit or prescribed by other practitioners or prescribers, and document within the patient record the plan after that discussion.'' N.J. Admin. Code §§ 13:35–7.6(f)(3), (f)(5). As already discussed, I find Dr. Kaufman to be more credible regarding documentation, and supported by New Jersey law.

(f) Effect on Prescriptions After an Inconsistent Urine Screen

Although the Government originally alleged in the OSC that every prescription after the initial prescription demonstrating an inconsistent urine screen was outside the usual course of the professional practice and beneath the applicable standard of care, Dr. Kaufman contradicted that allegation, stating ''[a]ny subsequent ones, if

[35] In further support of Dr. Kaufman's testimony, the New Jersey Office of Administrative Law has specifically held that ''summaries pieced together from memory long after the events sought to be recorded cannot substitute for timely record-keeping.'' *In the Matter of the Suspension or Revocation of the License of Magdy Elamir, M.D., License No. 25MA41404, to Practice Medicine and Surgery in the State of New Jersey,* OALK Dkt. No. BDS 01663–10 (Decided August 26, 2014). Respondent testified that one could conclude from her records when the prescription was issued despite the inconsistent urine screen that she ''had a good, good reason to write the next script;'' however, she also testified that she could not remember the results of her discussions. Tr. 1027; 1090–95 (Respondent testified that after L.M. tested positive for Suboxone three times in a row, she thought she had cut her dose, but she had not, and when asked for the reason, she stated, ''I don't remember, sir.'') Piecing together conclusions *post hoc* is not adequate recordkeeping to be able to understand the reason that she wrote the script or establish a plan moving forward. *See infra* Section III(A)(1)(b)(ii).

[36] Respondent argued that sometimes the laboratories err in showing positive urine screens and the urine must be retested; however, I saw no evidence in the record of screens being retested shortly after showing positive results for non-prescribed substances. *See* Resp Posthearing, at 43. Additionally, the fact that a screen might be inaccurate does not change the applicable standard of care as Respondent implies, but instead seems to highlight the need for documenting the resolution of the screens to ensure that the patient records are accurate as to what has actually occurred. *See* Resp Posthearing, at 43. I also find this argument unavailing, because if the screens were so inaccurate that they would not help Respondent identify issues with her patients, I do not understand why she ordered them every month at her own expense.

[37] It was unclear from his testimony whether he believed the applicable standard of care would require a conversation with the patient after a first positive test for fentanyl. He seemed to imply that a practitioner could assume that fentanyl was from a surgical procedure upon the first positive test, but the question of whether the practitioner would be required to discuss with the patient was not answered due to a sustained objection. Tr. 1598, 1600.

[38] Additionally, I do not find Dr. Epstein's testimony about the difference between what should be done and what is care to be convincing, because he also testified that ''[i]t's about providing the best possible care for the most possible people. . . .'' Tr. 718 (Dr. Epstein describing the standard of care).

they're having positive urine screens, would be appropriate. The one that was issued directly right after this urine screen would not be because this was not addressed.'' *Id.* at 250. Therefore, like the ALJ, I am only considering the prescriptions issued directly after an inconsistent urine screen. *See* RD, at 145.

4. Documentation of Alcohol Counseling

Dr. Kaufman testified that in order to meet the applicable standard of care in New Jersey a practitioner who was confronted with a urine screen that was positive for alcohol metabolites would need to ''discuss it with the patient and discuss the risks of alcohol with the use of opioids, of opiates, and to tell him to stop drinking'' and would need to document that discussion in the record. Tr. 212. Dr. Epstein testified that mixing oxycodone and alcohol is a ''very, very bad thing,'' and a practitioner must counsel his patient, and ''the standard of care is that, you know, if you're going to have a drink you shouldn't be doing it at the same time you're taking this pill.'' *Id.* at 1636. The Respondent does not dispute the ALJ's finding that a doctor must counsel a patient who has been prescribed an opiate and also has alcohol metabolites [39] in his urine about the dangers of concomitant alcohol and opioids. RD, at 120; Resp Exceptions, at 15 (''Respondent does not disagree with this statement.'') Dr. Kaufman testified that a prescription on May 5, 2017, to Patient A.P. was not issued within the usual course of the professional practice in New Jersey, because the ''positive alcohol screen . . . was never addressed.'' Tr. 213. He testified that one time drinking alcohol might not be problematic, but that ''you have to explain the dangers of doing that. One drink combined with one opioid can cause an overdose, just once. You may not get a second chance. You can be dead.'' *Id.* at 482. He also testified numerous times that documentation of the alcohol counseling was essential. *Id.* at 485–86 (''If it's not in the record, it didn't exist, because then you can't substantiate that. That's very important in medicine. That's how we talk to one another.'') [40] [41]

Additionally, Respondent testified that when alcohol appears in a drug screen, her usual practice is to counsel the patients and insert the alcohol entry for counseling in e-Clinical. *Id.* at 1013. She admitted that she may sometimes fail to click on the alcohol entry, because she is ''not 100 percent.'' *Id.* at 1013–14. Respondent's own practices demonstrate that she knows that documentation of the alcohol counseling is important, and furthermore, her system includes a shortcut key that permits her to specify that the alcohol-specific counseling occurred. *Id.*

Finding that counseling and its documentation is required when a urine screen shows alcohol metabolites, I also agree with the ALJ's finding that Respondent's selection of alcohol specific counseling is adequate to document the counseling. RD, at 124 n.68. Dr. Kaufman agreed that the ''counseling, alcohol and drugs . . . documented in the patient record . . . would [] be an appropriate way to deal with an alcohol screen.'' Tr. 214. This is further supported by the language in the state regulation regarding alcohol counseling that requires that the record ''note'' that the discussion took place and not the substance or the plan after that discussion. N.J. Admin. Code 13:35–76(d). In sum, I find that when a urine screen tests positive for alcohol metabolites, the applicable standard of care in New Jersey requires that a practitioner counsel regarding the dangers of alcohol and opioid use and document that counseling, and further that noting that the alcohol-specific counseling occurred is adequate for purposes of this case.

F. Allegations of Issuing Prescriptions Outside of the Usual Course of the Professional Practice and Prescribing Below the Applicable Standard of Care in New Jersey

Having read and analyzed all of the record evidence, I agree with the RD's conclusion and find that the substantial record evidence that Respondent prescribed controlled substances outside of the usual course of the professional practice and below the applicable standard of care in New Jersey. RD, at 139. The ALJ sustained the Government's allegations with regard to the five Vicodin prescriptions Respondent issued to the UC, and twelve of the twenty-one prescriptions that Respondent issued to patients A.P., J.C., L.M., M.W., and SW *Id.* In all, the ALJ found, and I agree, that ''between April 27, 2016, and March 8, 2018, [Respondent] issued a total of seventeen prescriptions on seventeen different occasions, to a total of six patients, which were issued outside the usual course of the professional practice and beneath the applicable standard of care in the State of New Jersey.'' *Id.* Although I agree with the ALJ's findings regarding these prescriptions, I make some additional findings as further explained below.

1. UC

The ALJ sustained the Government's allegations that Respondent issued five prescriptions for hydrocodone-acetaminophen (Vicodin), a Schedule II controlled substance, to the UC between November 23, 2016 and April 4, 2017, outside the usual course of the professional practice and beneath the applicable standard of care for the State of New Jersey in violation of 21 CFR 1306.04(a), because she failed to conduct a physical exam at each of the

[39] Throughout the hearing, there was discussion about the difference between alcohol and alcohol metabolites on the urine screen and whether the presence of the metabolites indicated less of a concern than the presence of alcohol. *See, e.g.,* tr. 1632. Dr. Epstein testified that an alcoholic's urine would show more than just metabolites, but his testimony seemed to be focused on alcoholics, because alcoholism was relevant to whether or not a practitioner be required under the standard of care to stop prescribing opioids ''because it's addictive behavior.'' Tr. 1634. More importantly, he testified that you have to counsel about the dangers of mixing alcohol and opioids even when the urine shows metabolites. Tr. 1636. I am setting aside the issue of metabolites, because I am only making findings on the counseling and documentation, not the dismissal of the patients, and furthermore, Respondent has conceded that a doctor must counsel when metabolites are present. Resp Exceptions, at 15.

[40] Dr. Kaufman's testimony was clear about the requirement under the applicable standard of care to counsel regarding alcohol and the requirement to document that counseling. *See* tr. 212. However, he also testified that a practitioner must cease prescribing opioids in the face of urine screens consistently demonstrating alcohol metabolites, and he stated that the standard of care required a practitioner to counsel twice regarding alcohol before terminating the medication. *Id.* at 471–473; RD, at 43. The ALJ found that this testimony ''undercuts his own testimony concerning several of the prescriptions to A.D. and SW'' RD, at 119. I agree with the ALJ that Dr. Kaufman's testimony regarding when to terminate a patient was confusing, and because of that confusion, I am not finding any violations on the basis that any of the patients' prescriptions should have been terminated for positive alcohol tests. However, I do not find that he undercut his previous testimony, because Dr. Kaufman was testifying about two different scenarios under the standard of care. In one scenario, he was testifying that a particular prescription ''was issued in light of positive urine screen for alcohol, which was not addressed at all.'' Tr. 251; 251–256; 257 (''in light of an aberrant urine screen, there was no counseling.'') In the other scenario, he was responding to Respondent's counsel's question ''assuming a person follows the standard of care and counsels against using alcohol or other drugs . . . they can then prescribe maybe another prescription for narcotics, is that right?'' Tr. 467.

[41] New Jersey's regulation (d) requires a discussion about risks that shall include ''the danger of taking opioid drugs with alcohol'' before the initial prescription and prior the third prescription and additionally states, ''The practitioner shall include a note in the patient record that the required discussion(s) took place.'' N.J. Admin. Code 13:35–76(d). Although this regulation does not specifically require that alcohol counseling must occur upon a positive urine screen, and is therefore not being alleged as a regulatory violation in this case, it does very specifically state that the counseling must be documented.

UC's visits.[42] RD, at 122–23; OSC, at 2. At each appointment, the UC complained of right shoulder pain or tightness. RD, at 46 (citing GX 18, 19, 21, 23, 25, 27; Tr. 46, 51, 56–57, 62, 66, 75, 100). The ALJ found, and I agree, that the allegations were proven through the testimonies of Dr. Kaufman and Dr. Epstein,[43] and to a lesser extent through Respondent and Dr. Gutheil based on the applicable standard of care in New Jersey. RD, at 122–23. Dr. Kaufman credibly testified that the applicable standard of care in New Jersey required a physical exam prior to prescribing controlled substances, and that Respondent should have ''examine[d] the shoulder where the primary complaint was, other than observing the patient.'' Tr. 391. He further explained that a minimal physical examination of the shoulder is ''certain maneuvers such as a Neer's test, a Hawkins' test, an Apley's test, an O'Brien's test, a reduction of the shoulder, intrinsic rotation of the shoulder, palpation of the AC joint, palpation of the bursa, palpation of the muscle; basic shoulder exam.'' [44] *Id.* at 378.

During the hearing, Respondent admitted that she did not palpate the UC's shoulder or touch the UC. RD, at 122 (citing tr. 878–79).[45] Additionally, the UC credibly testified that Respondent did not give her a physical exam or touch her on any of the visits. Tr. 45, 51, 57, 62, 66, 75. Respondent argued that observation of the patient, his or her presentation, speech, and carriage was part of the physical exam, which Dr. Kaufman conceded may be a ''small component,'' but is ''woefully inadequate and below standards.'' *Id.* at 386, 390. Dr. Kaufman further testified that a physical exam is required each time controlled substances are issued based on the applicable standard of care and the regulation, which ''stipulates that an appropriate physical exam must be conducted.'' *Id.* at 399. When asked if a physical examination was still necessary if a physician had a recent MRI showing a problem, Dr. Kaufman testified that ''[i]t's still necessary.'' *Id.* at 397.

Respondent argued that she had required the UC to obtain a new MRI before prescribing controlled substances, and she testified that when she reviewed the second MRI, she was able to make a diagnosis that the UC had arthritis. *Id.* at 823–24; GX 29, at 24; Tr. 865 (Respondent testified that because pain is subjective, she relies on results of MRIs ''about 90 percent of the time''). However, Respondent did not include her alleged diagnosis of arthritis in the UC's treatment notes. RD, at 57 (citing GX 19 [46]). Instead, the assessment section lists ''pain in right shoulder'' and ''chronic pain syndrome.'' GX 29, at 13; tr. 1057–58; RD, at 57. Further, Respondent's own recorded statements at the UC's third appointment undermine her testimony that she had made a diagnosis based on the second MRI.[47] Tr. 824. In the recorded conversation, the UC reminded Respondent that she received a new (second) MRI, ''[c]ause I got—from the first time to the second time, I got a different—I got uh, updated MRI,'' and Respondent replied, ''Right. And [it] still didn't show anything, sweetheart.'' GX 14, at 11; *see also* RD, at 59.[48] This statement clearly undermines Respondent's testimony that she had a clear diagnosis from the MRI to justify prescribing to the UC.[49]

After reviewing the record evidence, including the video and audio recordings of the UC's visits with Respondent, I agree with the ALJ's finding that, Respondent did not perform an adequate physical examination of the UC at any of the UC's appointments. RD, at 46.

Based on the fact that Respondent did not perform an adequate physical examination, as required by the applicable standard of care in New Jersey, the ALJ found, and I agree, that the prescription for Vicodin issued to the UC at her second appointment on November 23, 2016, was issued outside the usual course of the professional practice of medicine. RD, at 58 (citing Tr. 179–80, 878–79, 1442; GX 20). Additionally, I agree with the ALJ that the prescriptions Respondent issued to the UC for: Vicodin on December 22, 2016; Vicodin on January, 19, 2017;

[42] The Respondent's treatment notes for each visit with the UC indicate that physical examinations were performed on each visit; however, the UC testified that they did not and the video recordings did not demonstrate palpation or otherwise adequate physical examination. Tr. 176; GX 29.

[43] As the ALJ noted, Dr. Epstein initially testified that prescriptions to the UC met the standard of care; however, in formulating his opinion, it was clear through his testimony that he had relied on the treatment record for UC, which had detailed a physical exam, which the Government proved through video evidence and testimony did not occur. *See* RD, at 122 (citing tr. 1435; tr. 1614; GX–6). ''Dr. Epstein testified that his opinion would change . . . if [Respondent] had not conducted a physical examination.'' RD, at 123 (citing tr. 1527). *See also supra* II(E)(2).

[44] Respondent argued that ''Dr. Kaufman could not explain the minimum examination required for a shoulder complaint.'' Resp Exceptions, at 13. Respondent's argument taken in context of the transcript is not convincing. When pressed by Respondent's attorney to quantify how many of those nine tests would constitute and minimal shoulder examination, Dr. Kaufman stated, ''There is no strict number, whether you need to do two or three or four, but you need to do something'' and then stated, ''You need to do something to elucidate what the problem is.'' Tr. 379. Respondent's attorney then asked, ''Maybe one thing?'' Dr. Kaufman responded, ''One thing is not enough. If you do one thing, you're only checking one aspect of the shoulder.'' *Id.* Respondent's attorney continued to push to try to find out ''what [Respondent] needed to do to meet the threshold where you would say, No, this was okay.'' *Id.* at 380. Dr. Kaufman answered, ''She didn't do anything.'' *Id.* The facts demonstrate that Dr. Kaufman specifically testified to the components of a standard shoulder examination and he credibly testified that the number of tests that would need to be included in an examination of the shoulder to meet minimal standards is not essential in this instance, because Respondent did not conduct *any* of these tests on the UC. The argument that Respondent conducted part of a physical examination does not change Dr. Kaufman's credible testimony that any such examination was beneath the applicable standard of care in New Jersey.

[45] Respondent's testimony directly contradicted a portion of the video that her attorney attempted to argue that she may have briefly touched the UC. Tr. 868. Later, it is noted that the attorney asked Respondent about her inconsistent statements with regard to whether she touched A.P. and she stated, ''I saw her in 2016, so my memory is not that great.'' *Id.* at 1017. Upon reviewing the video, I agree with the ALJ's statement in the hearing that this movement is ''pretty insignificant given the fact that there was a desk between the two of them.'' *Id.;* GX 6, 0320.010, at 9:53–9:57.

[46] GX 19 is a one page extract of the UC's second visit. The same record is also found in GX 29, at 13.

[47] Despite this claim, Respondent responded affirmatively to the question, ''Couldn't you have learned more from a physical examination?'' Tr. 824–25.

[48] Further, in defending the lack of physical examination, Respondent stated, ''[I]n my clinical judgment, the way I observed [UC], even second time, third time, fourth time, [UC's] arm, the range of motion was good. And, I prescribed her the little amount that I thought was sufficient.'' Tr. 1067. It is unclear to me even from Respondent's testimony what her justification was for the prescriptions she issued to the UC. Additionally, this statement undermines her argument that she performed the physical examination by watching the UC, because the UC patient records list under Physical Examination, ''Right Shoulder Tenderness,'' which would imply that Respondent saw something indicating tenderness during her observation. *See, e.g.,* GX 18, at 1.

[49] Respondent did mention arthritis in some of the UC transcripts, which she appeared to base on the MRI. *See, e.g.,* GX 13, at 7. However, on several subsequent visits, during which she prescribed controlled substances, she did not seem to have access to the MRI before she made any of the prescribing decisions. On December 22, 2016, she asked, ''[T]he reason we were giving you narcotic, we discussed that before, right? It was for what reason, sweetheart?'' And then, ''I mean, what was your diagnosis with the other doctor? I got me some records, right, before?'' GX 14, at 11. On the same visit, Respondent said she could not increase the dosage without x-rays showing something and she never seemed to find the MRI. *Id.* She stated, ''If it's just bursitis, I can't do it.'' *Id.* at 13. On January 19, 2017, she asked, ''[W]ere you able to give me the MRI of the ankle, right from the place?'' UC asked, ''Ankle? No, that wasn't me.'' Respondent said, ''Soft tissue injury, you had . . . sorry, not ankle, the shoulder.'' GX 15, at 5. Again, on March 7, 2017, Respondent asked the UC, ''I didn't have any MRI's, nothing from you, right?'' GX 16, at 9. These statements further contradict Respondent's testimony that she relied on the UC's MRI in lieu of a physical examination as a basis for her prescriptions.

Vicodin [50] on March 7, 2017; and Vicodin on April 4, 2017, did not meet the applicable standard of care in New Jersey and were issued outside the usual course of the professional practice of medicine, because Respondent never performed a competent physical examination of the UC. RD, at 62, 64, 68, 71 (citing GX 22, 24, 26, 28; tr. 191–93, 195, 878–79, 1442).

The ALJ did not sustain the alleged violation of the applicable standard of care that Respondent recorded the results of a complete physical in the UC's medical record, even though the exam did not occur. RD, at 139. He reasoned that he could not find a recordkeeping violation ''because it was not alleged as a separate violation in the OSC, and the Government did not detail in either of its prehearing statements how this false entry was a separate violation.'' *Id.* The Government did not take exception specifically to this finding, but urged that the false recordkeeping demonstrated that ''Respondent's medical records grossly overstate the care provided.'' Govt Exceptions, at 20. The Government laid out numerous inconsistencies in the records, related to when Respondent's records for the UC reflect that counseling occurred, when the transcripts demonstrate that it did not. *Id.* at 21–22; *e.g.,* tr. 52 (UC confirming no counseling occurred); GX 18, at 2 (Respondent's medical record for UC noting that counseling about medication and smoking occurred). I agree with the ALJ that there was no specific violation alleged with regard to falsely documenting the physical examination, and therefore, I concur with the ALJ and sustain no violation on that account. I also agree with the Government that the fact that the UC's medical records reflect a detailed physical exam that was not, in fact, conducted, and counseling that never occurred,[51] casts serious doubt upon the other records Respondent maintained and is relevant to the Respondent's overall credibility.

2. Patient A.P. Alcohol Allegations

The stipulated facts demonstrate that between and including June 6, 2016, and April 5, 2018, Respondent issued prescriptions for controlled substances to A.P. on twenty-three occasions. *See* Stipulations 4(a)–(v). In this time period, A.P. submitted a total of nineteen urine samples for screening. RD, at 73–74. The ALJ found, and I agree, that A.P.'s urine screens were positive for alcohol metabolites on May 5, 2017; July 8, 2017; August 10, 2017; September 7, 2017; October 5, 2017; and February 8, 2018. RD, at 75 (citing Stipulations 5(a), (c)–(f), (h); GX 54, 60, 63, 69, 79). The ALJ found that on August 10, 2017, (following the July 8, 2017 alcohol metabolite positive urine test) and September 7, 2017,[52] (following the August 10, 2017 alcohol metabolite positive urine test), Respondent's patient records for A.P. indicate that she provided expanded and alcohol specific drug counseling. GX 61, 64. On direct examination at the hearing, Dr. Kaufman testified that A.P.'s patient notes for these visits demonstrate that specific discussions about alcohol counseling occurred on these two occasions. Tr. 214–15. Therefore, the ALJ found that the two prescriptions issued on these dates did not violate the applicable standard of care related to alcohol counseling. RD, at 75. I do not believe that Dr. Kaufman provided sufficient evidence to rebut the Respondent's arguments that this level of documentation with regard to alcohol screening was adequate under the applicable standard of care, and even though I have serious doubts regarding the credibility of Respondent's testimony and records in this case, I will concur with the ALJ and weigh alcohol-specific counseling documentation in her favor. However, the ALJ found, and I agree, that counseling occurred only when the patient records specifically indicated that alcohol counseling was provided. RD, at 124 n.68. Therefore, the prescriptions [53] resulting from the visits on October 5, 2017, (following the September 7, 2017) and March 8, 2018,[54] (following the February 8, 2018 alcohol positive urine screen) were not issued within the applicable standard of care for New Jersey, because there was no documentation of the alcohol counseling. RD, at 126–127; *see also,* tr. 219–20 (Dr. Kaufman testified that ''continued permissive alcohol use and continuance of opioids puts a patient in a dangerous situation. Therefore, it should not have been issued.'') The ALJ did not sustain the allegations related to the June 8, 2017, prescription following the alcohol positive urine screen that occurred on May 5, 2017, despite the fact that Respondent did not document her alcohol counseling, because the ALJ did not believe it would be appropriate to terminate the prescriptions after the first screen demonstrating alcohol use. RD, at 124 (citing RD 117–20). I respectfully disagree with the ALJ's

[50] Although the ALJ found that on March 7, 2017, the Respondent's issuance of the prescription for tramadol (brand-name Ultram) did not meet the applicable standard of care in New Jersey, the ALJ ultimately did not sustain a violation related to tramadol, because the Government failed to allege the violation associated with this prescription in the OSC or either of its prehearing statements. RD, at 101 n.49. I agree with the ALJ that the Government did not mention the prescription for tramadol or Ultram in any of its prehearing documents, nor did it count this prescription in the number of violations related to UC. The Government argued that it raised the Ultram prescription specifically during the hearing, in which Dr. Kaufman testified that the prescription was issued below the applicable standard of care, and therefore it was litigated by consent. Govt. Exceptions, at 8, n.3 (citing Tr. 191–192); *see also* Govt Post Hearing, at 4. The analysis of litigation by consent is fact specific. *See Farmacia Yani,* 80 FR at 29,059. '' 'An agency may not base its decision upon an issue the parties tried inadvertently. Implied consent is not established merely because one party introduced evidence relevant to an unpleaded issue and the opposing party failed to object to its introduction. It must appear that the parties understood the evidence to be aimed at the unpleaded issue.' '' *Id.* (quoting *Yellow Freight System, Inc.* v. *Martin,* 954 F.2d 353, 358 (6th Cir. 1992)). The Government had ample opportunity to include this prescription to its own undercover agent and, in this case, Respondent's counsel did not indicate any sort of consent other than failing to object, so I am not sustaining this allegation. *See* tr. 191–191.

[51] *See, e.g.,* GX 18, at 2 (smoking counseling noted that never occurred); GX 18, 19, 21, 23, 25 (physical examination never occurred).

[52] Dr. Kaufman testified that the discussion on September 7, 2017, was appropriate for someone who had tested positive for alcohol two times in a row, but then testified that the prescription dated September 7, 2017, was not issued within the usual course of the professional practice, because Respondent ''in her notes, clearly stated to the patient twice, do not use alcohol with drugs, do not use alcohol with drugs.'' Tr. 216. Respondent had issued the second warning to the patient on the date of this prescription. *See* GX 64, 65. At this point, although A.P. had tested positive three times for alcohol (May 5, 2017, July 8, 2017, and August 10, 2017), Respondent had only *documented* counseling the patient twice (one of which was on the day of the prescription in question). The ALJ pointed out what he described as an inconsistency, that in accordance with Dr. Kaufman's later testimony, the applicable standard of care does not require a practitioner to terminate the controlled substances on the third visit following two inconsistent urine screens. RD, at 125–26 (citing Tr. 472). The ALJ is correct about the substance of Dr. Kaufman's testimony, but I do not believe that this part of his testimony was inconsistent. The confusing matter in this instance is that this was, in fact, the *fourth* visit, not the *third* and there had been *three* urine screens demonstrating alcohol, not *two.* The discussion related to the first positive urine screen had simply not been documented or had not occurred. I note this merely to clear up what the ALJ considered to be an inconsistency with the Government expert's testimony; however, as stated previously, I am only finding violations for alcohol where counseling was not documented, not on the basis of dismissal. *See supra* note 39; *see also* RD, at 120.

[53] Respondent pointed out that there was an additional unalleged positive test for alcohol on October 5, 2017, but the prescription issued on November 3, 2017, was not addressed by the Government. Resp Posthearing, at 26 n.15; GX 59. I agree that this was not appropriately alleged and will not include any findings on the November 3, 2017 prescription. The RD did not address this prescription either.

[54] Respondent alleged that the March 8, 2018 prescription was not alleged in the OSC; however, the prescription following the February 8, 2018 urine screen was noticed in the Government's Supplemental Prehearing statement. Resp Posthearing, at 26, n.15; Govt Supp Prehearing, at 5–6.

determination regarding this prescription. Dr. Kaufman testified that this particular prescription was not issued within the usual course of the professional practice for New Jersey because, the ''positive alcohol screen . . . was never addressed.'' Tr. 213. As discussed previously, the ALJ had found the prescription on March 8, 2018, to be issued below the applicable standard of care in New Jersey, because Respondent ''did not document what she told him about consuming alcohol while also taking a prescription opiate,'' which would be the same rationale for the June 8, 2017 prescription. RD, at 127. I find that Government has proven by substantial evidence that a prescription issued after a positive urine screen for alcohol with no documentation of alcohol counseling does not meet the applicable standard of care in New Jersey, and therefore, I find that the prescription issued on June 8, 2017, was also issued beneath the applicable standard of care. *See infra* Section II(E)(4).

3. Patient A.P. Inconsistent Urine Screening

The ALJ found, and I agree, that Patient A.P. tested negative for opioids [55] on June 8, 2017, and January 8, 2018.[56] RD, at 73–74; GX 57, 73. The ALJ conducted a thorough evaluation of the New Jersey Prescription Monitoring Program (hereinafter, PMP) [57] records to determine the number of days between the date that the PMP indicated that A.P. filled the prescription [58] and the date that his urine tested negative for oxycodone. RD, at 73–74 (citing ALJX 45 (PMP), at 6). The ALJ analyzed these dates in a chart with the amount of tablets in the prior prescription to determine whether it was reasonable for Respondent not to have documented the inconsistent urine screen.

Dr. Kaufman testified that a January 8, 2018 urine screen that tested negative for opiates following a prescription that was issued on December 7, 2017, thirty-three days prior to the drug screen, was inconsistent, and therefore the prescription issued on February 8, 2018, following Respondent's knowledge of the results of that drug screen was issued outside the usual course of practice for the State of New Jersey. Tr. at 210. Dr. Kaufman reasoned that it was outside the usual course of the professional practice because ''[t]hat urine screen was never addressed, it's almost as if it didn't happen.'' *Id.* at 210–11. The ALJ found that because this urine screen was within thirty-three days of the fill date, there was no requirement for documentation of the screen, because he had found that the Government's evidence had only established the requirement at thirty-two days. RD, at 126. As explained above in *supra* Section II(E)(3)(b), I found that the Government established that the threshold for counseling and documentation of an inconsistent urine screen was more than thirty-three days; and therefore, I sustain the allegation that this prescription was issued beneath the applicable standard of care, because the Respondent should have documented a discussion with the patient about the inconsistent results and the plan to address it.

Dr. Kaufman testified that the urine screen on June 8, 2017, was inconsistent with the prescribed opioids; however, the ALJ found that the allegation regarding the prescription could not be sustained because it had been thirty-five days since A.P. had filled the prescription on May 5, 2017. RD, at 76. Due to the fact that the Government's expert testified that a negative urine screen would not be concerning thirty-three days after the prescription was filled, I agree with the ALJ that the Government has not proven that the prescription on July 6, 2017, after the results of the negative urine screen on June 8, 2017, was issued outside of the usual course of the professional practice and below the applicable standard of care in New Jersey, based on the negative urine screen.[59] RD, at 124–25.

Overall, with respect to Patient A.P, I find that the prescriptions issued on October 5, 2017; June 8, 2017; March 8, 2018 were issued below the applicable standard of care in the State of New Jersey, because there was no documented alcohol counseling, and the prescription on February 8, 2018, was issued below the applicable standard of care in the State of New Jersey, because there was no documented discussion related to the inconsistent urine screens.

4. Patient J.C.

The stipulated facts demonstrate that between and including August 22, 2016, and April 10, 2018, Respondent issued prescriptions for controlled substances to J.C. on twenty-one occasions. *See* Stip. 6(a)–(t); *see also* RD, at 77–78. In this time period, J.C. submitted a total of sixteen urine samples for screening. RD, at 78. The ALJ found, and I agree, that J.C.'s urine screens were negative for oxycodone on October 19, 2016, June 20, 2017, July 25, 2017. RD, at 78–79 (citing GX 88; GX 130, at 63; GX 130, at 53; GX 130, at 51; Stip. 7(a), 7(b) and 7(c)).

The ALJ conducted a thorough evaluation of the PMP records to determine the number of days between the date that the PMP indicated that J.C. filled the prescription and the date that his urine tested negative for oxycodone. RD, at 78–79 (citing ALJX 45, at 2–3 (PMP)). The ALJ analyzed these dates in a chart with the amount of tablets in the prior prescription to determine whether it was reasonable for Respondent not to document the inconsistent urine screen. *Id.*

Dr. Kaufman testified that a October 19, 2016, urine screen that tested negative for opiates following a prescription that was issued on September 21, 2016 (seventeen days prior to the drug screen) was inconsistent, and therefore the prescription issued on November 17, 2016 following Respondent's knowledge of the results of that drug screen was issued outside the usual course of the professional practice in the State of New Jersey. Tr. 223. J.C. testified that Respondent always counseled him on the negative test results and asked him why he was not taking his medication and J.C. further testified that he told Respondent that his pain was too intense, so he used all of the medication. RD, at 80 (citing tr. 853,

[55] In the OSC, the Government ''incorrectly alleged that A.P.'s urine screen of May 5, 2017, tested negative for oxycodone.'' RD, at 124 (citing ALJX 1, at 2–3). The Government's Supplemental Prehearing Statement concedes that this was incorrect. G's Supplemental Prehearing, at 2. The OSC does allege that all prescriptions after November 3, 2016, were issued outside the usual course of the professional practice without giving a rationale for this finding, so it appears that the Government might have mixed up the May 5, 2017 date with November 3, 2016 (*see infra* note 55), but I am not including findings on November 3, 2016, either because it was not adequately noticed. ALJX 1, at 3.

[56] The ALJ also included in his chart two other dates where A.P. tested negative for opiates, November 3, 2016, and April 5, 2018. RD, at 73–74 (citing GX 84, at 98 and 123). The Government did not allege any violations related to these two tests in the OSC, nor in either the Prehearing Statement or Supplemental Prehearing Statement or the Posthearing Brief. The ALJ does not address these two inconsistent urine screens in his final findings on the allegations, and I agree that this was appropriate, so I will not consider them.

[57] The Government introduced the PMP records in GX 2 and 3, and the ALJ presented an excerpt of the 6 patients' records to the parties for comment at the conclusion of the hearings, upon which he relied in his RD. Tr. 1646.

[58] It appears that on almost every negative urine screen in this case, the prescription was filled on the same date it was issued; therefore, I am only distinguishing the fill date where relevant, and I incorporate the RD's charts in this decision.

[59] However, I find below that this prescription was issued beneath the applicable standard of care and outside the usual course of the professional practice because of the undocumented alcohol counseling.

935, 974–75, 978–79, 993–94, 1046, 1343–45, 1354). Although Respondent testified that she always counseled J.C. following the inconsistent urine screens, the patient notes for J.C. do not reflect additional counseling or what was discussed and what the plan was moving forward with treatment. *Id.; see also,* RD, at 80 (citing GX 92, 109, 112). Due to the Respondent's lack of documentation regarding the counseling that she asserts occurred, I agree with the ALJ that the prescription issued on November 17, 2016, was issued outside the usual course of the professional practice and below the applicable standard of care in the State of New Jersey. RD, at 128.

On June 20, 2017, J.C. tested negative for opiates despite the fact that he had been prescribed thirty days of Roxicodone thirty days prior to the urine test on May 11, 2017. Dr. Kaufman testified that the prescription issued to J.C. on July 25, 2017, was ''not issued within the usual course of practice, because it 'was issued after the negative urine screen, without counseling of the urine drug screen as to why it was negative . . .' for opiates.'' RD, at 81 (citing tr. 227, GX 109, 110). Due to the Respondent's lack of documentation regarding the counseling that she asserts occurred, I agree with the ALJ that the prescription issued on July 25, 2017, was issued outside of the usual course of the professional practice and below the applicable standard of care in the State of New Jersey. RD, at 129.

On July 25, 2017, J.C. tested negative for opiates despite the fact that he had been prescribed thirty days of Roxicodone thirty-four days prior to the urine test on June 20, 2017. The ALJ applied the measuring unit of thirty-two days to determine when the applicable standard of care would require counseling and found that the subsequent prescription on August 22, 2017, was issued within the usual course of the professional practice. RD, at 129. Although I believe the appropriate test is 33 days, I agree with the ALJ that the Government has not proven by substantial evidence that this prescription was beneath the applicable standard of care in New Jersey. RD, at 129.

Overall, with respect to Patient J.C., I find that the prescriptions issued on November 17, 2016, and July 25, 2017, were issued below the applicable standard of care in the State of New Jersey, because there was no documented discussion related to the inconsistent urine screens.

5. Patient L.M.

The stipulated facts demonstrate that between and including September 28, 2015, and May 24, 2017, Respondent issued prescriptions for controlled substances to L.M. on twenty-three occasions. *See* Stip. 8(a)–(u); *see also* RD, at 82–83. In this time period, L.M. submitted a total of fourteen urine samples for screening. RD, at 84. The ALJ found, and I agree, that L.M.'s urine screens showed inconsistent results on May 17, 2016;[60] June 13, 2016; July 12, 2016;[61] January 31, 2017; and April 26, 2017. RD, at 84–85; GX 175, at 144; GX 175, at 141; GX 175, at 139; GX 175, at 131; GX 175, at 123; Stip. 9(a), 9(b) and 9(c)).

Respondent testified that when L.M. tested positive for Suboxone, she had called the lab and the lab had said to recheck the urine ''[a]nd I tested her again; she didn't come back positive the next time.'' Tr. 857. This description of the events is undermined by the evidence on the record that shows that L.M. tested positive three times in a row for Suboxone and Respondent's own later testimony. *See infra* note 60; tr. 1092–95. Dr. Kaufman testified that on June 13, 2016, L.M.'s urine screen tested positive for norbuphrenorpine or Suboxone, which is ''generally used for controlled substance withdrawal'' and in order to meet the minimum standard of care in New Jersey a practitioner would need to address why the patient tested positive for Suboxone. Tr. 258–59. Dr. Kaufman testified that he would ''expect to see a note such as I discussed with the patient the positive urine screen for metabolite of Suboxone. I questioned the patient as to where they were getting this, why were they getting this? . . . . [a]nd could they be inadvertently hurting themselves because they're now taking two controlled substances?'' Tr. 260. Dr. Kaufman testified that he was particularly concerned that the PMP did not reflect that this medication was prescribed, which indicates that the patient could be receiving it illicitly and that the patient needed to know about safety issues of taking two controlled substances. *Id.* at 262–63. Respondent[62] testified that she counseled L.M. about the Suboxone in her urine and she realized by the third visit when L.M. had tested positive three times in a row that the counseling was not successful, but she could not explain why she had not subsequently reduced the dose of Percocet for L.M. Tr. 1092–95. She believed that Suboxone was not ''a street drug'' and that the patient had likely received it from a hospital for withdrawal. *Id.* The fact that Respondent cannot remember why she continued to issue prescriptions for L.M. after she tested positive for Suboxone underscores the importance of maintaining adequate records resolving the inconsistent urine screen. The ALJ found, and I agree, that the prescriptions on the date following urine screen demonstrating Suboxone were not issued within the usual course of the professional practice in New Jersey ''because [Respondent]'s records for L.M. on July 12, 2016, following the June 13th urine test, did not document how she resolved the fact that L.M.'s urine screen was positive for Suboxone.'' RD, at 130 (citing his Finding of Facts (hereinafter, FF) 34, 79, 189).

On January 31, 2017, L.M.'s urine sample tested positive for fentanyl, which was not prescribed by Respondent. GX 175, at 129. Respondent stated that she ''called the primary care and [she] asked for their note'' and they ''told [her] over the phone that they ordered a

[60] Despite that the prescription on June 13, 2016, was issued after testing positive for Suboxone and fentanyl on May 17, 2016, the Government did not address this in any of its filings nor its testimony, so I am not including a violation for this date. GX 175, at 144.

[61] On July 12, 2016, for the third time in a row, the records demonstrate that Patient L.M. tested positive for Suboxone, but the Government did not reference this date in its OSC or prehearing statements or in the presentation of its case at the hearing. That being said, the Respondent raised the fact that L.M. had tested positive for Suboxone three times in a row. Tr. 1092–95. I will not include a specific finding regarding the prescription following this screen on August 18, 2016; however, I believe that the record adequately demonstrates that L.M. tested positive three times in a row for Suboxone—a fact which enhances the egregiousness of Respondent's overall prescribing to this patient. GX 147; Tr. 1092–95; *see also* (Govt Posthearing, at 10 n.3 (admitting that the Government did not charge this prescription, but proposing that it demonstrates that the buprenorphine/Suboxone ''was not an isolated incident.'').

[62] The ALJ stated that Respondent credibly testified that she had counseled the patient here. *See* RD, at 130. However, earlier he had found Respondent's credibility regarding the Suboxone prescriptions to be problematic, because her explanation that the patient ran out of the oxycodone that she had prescribed and then went to a clinic or hospital to get Suboxone for withdrawal were not plausible. RD, at 23; *see* Tr. 1099–1101. On June 13, 2016, and July 12, 2016, Patient L.M.'s urine testified positive for BOTH Suboxone and Oxycodone. GX 175, at 139; GX 175, at 131. If she had received Suboxone for withdrawal symptoms, then it does not make sense that she would still have tested positive for the oxycodone, unless she had received it illicitly. *See also* RD, at 23. I do not find Respondent to be credible that she counseled the patient about this test, because her explanation based on that counseling is implausible; however, as stated earlier, I am not resting my finding of a violation on the existence of counseling, but instead upon the non-existence of its documentation.

colonoscopy''; however, if such a call occurred, it was not documented in the patient record. Tr. 856. The ALJ determined, and I agree, that the prescription issued on February 28, 2017, following the January 31st inconsistent test, ''was not issued within the usual course of practice of medicine in New Jersey because [Respondent] did not document that she resolved the 'clearly aberrant urine screen . . . for [] [f]entanyl.'' RD, at 131 (citing tr. 265; FF 79, 192).

On April 26, 2017, Patient L.M.'s urine sample tested positive for 6–MAM, a heroin metabolite. RD, at 131; GX 175, at 126. On L.M.'s subsequent appointment with Respondent on May 24, 2017, L.M.'s patient records demonstrate that Respondent discharged the patient for heroin; however, she also issued L.M. a prescription for 90 Percocet 5/325 milligrams. RD, at 131; *see also* tr. 550; GX 173 (''D/C UDS positive for heroin''); GX 174 (prescription). Dr. Kaufman testified that the only information in the patient record was that the patient was discharged for heroin. There was no additional explanation of counseling. Tr. 551. Dr. Kaufman testified that the applicable standard of care upon a urine screen positive for heroin would be ''to stop [prescribing opioids] and treat any withdrawal symptomology.'' Tr. 557. He testified that it would be within the applicable standard of care to prescribe a small amount of medication ''with a very specific weaning schedule for that patient.'' *Id.* at 562. Respondent did reduce [63] the amount of her prescription to L.M., which she characterized as a ''weaning script.'' Tr. 1061.

Dr. Kaufman testified that Respondent did address the positive heroin test, because ''she discharged [L.M.] from the practice.'' Tr. 564; *accord id.* at 566. He also answered affirmatively to Respondent's counsel's question that it *could* be within the standard of care to issue a weaning dose upon the discharge. Tr. 565 (emphasis added). The ALJ concluded that on cross examination, Dr. Kaufman had testified that Respondent's reduction of the dose of L.M.'s prescription on her last visit was within the applicable standard of care. RD, at 132 (citing tr. 562–63). I agree that both the questions and the answers during this part of the hearing were confusing, but I do not agree with that conclusion. Dr. Kaufman answered, ''That's correct'' after a lengthy question containing a double negative and ending with ''it's your conclusion that this [presumably L.M.'s chart] doesn't indicate that this was outside the standard of care, is that right?'' Tr. 562–63. From my reading of the testimony, this response was not necessarily inconsistent, because Dr. Kaufman testified several times that the chart does not state anything about the reason for the prescription, so it does not make logical sense that a chart with no explanation could indicate whether or not the prescription was intended for weaning.[64] In fact, the chart does not indicate one way or another that it was a weaning prescription, and that is the ultimate reason why I find that this prescription was issued beneath the applicable standard of care.[65]

Furthermore, when the Government followed up with Dr. Kaufman on this issue, he clarified that weaning a patient would require documentation in the record, and also would include directions ''written on the prescription to give the patient the proper directions on how to do it''; therefore, the prescription was ''not necessarily'' a weaning prescription. Tr. 654–55. Dr. Kaurman also affirmed that the prescription was outside the applicable standard of care. *Id.* Even though Respondent had followed the applicable standard of care in discharging the patient after the heroin was discovered, I believe that the Government has established by substantial evidence that, the prescription issued on May 24, 2017, was issued outside the usual course of the professional practice and beneath the applicable standard of care in New Jersey, because Dr. Kaufman credibly testified that the applicable standard of care required that a weaning prescription be documented as such and provide weaning instructions to the patient. *See id.* Without adequate recordkeeping, there is no indication of the intent of the prescription or the fact that counseling occurred.[66]

6. Patient M.W.

The stipulated facts demonstrate that between and including January 30, 2015, and August 25, 2017, Respondent issued prescriptions for controlled substances to M.W. on thirty-two occasions. *See* Stip. 10(a)–(ff); *see also* RD, at 87–89. In this time period, M.W. submitted a total of nineteen urine samples for screening. RD, at 89, 133. The ALJ found, and I agree, that M.W.'s urine screens showed inconsistent results for someone who has been prescribed opioids on May 3, 2016 (thirty days since filled), July 8, 2016 (fifteen days since filled), and July 28, 2017 (thirty days since filled). RD, at 89–90; GX 207, 242; Stip. 11(a), 11(b) and 11(d).[67] There was no documented counseling that specifically addressed any of the inconsistent urine screens. RD, at 87–92; GX 259, at 60–61, 62–63, 92–93; Stip. 10(m), 10(ee), 10(ff). Therefore, the ALJ found, and I agree, that the Government has proven by substantial evidence that the prescriptions issued on May 27, 2016, August 5, 2016, and August 25, 2017, following the inconsistent urine screens were issued beneath the applicable standard of care and outside of the usual course of the professional practice in New Jersey. *See* RD, at 91–92; GX 209, 216, 244.

7. Patient S.W.

The stipulated facts demonstrate that between and including March 16, 2015, and April 6, 2018, Respondent issued prescriptions for controlled substances to S.W. on thirty-nine occasions. *See*

[63] During the two preceding visits on March 30, 2017, and April 26, 2017, Respondent had prescribed L.M. two prescriptions for Percocet. GX 175, at 64 (prescription for 90 tablets of Percocet 5/325); RX 9, at 2 (prescription for 30 Percocet 10 miligrams).; Tr. 560. The ALJ noted that the PMP confirmed the two prescriptions. RD, at 131 (citing ALJX 45, at 5).

[64] This response makes more sense when read along with Respondent Counsel's preceding question, ''So do you have any reason to believe that Doctor, from this chart, that [Respondent] didn't provide a weaning schedule?'' to which Dr. Kaufman responded, ''I don't.'' Tr. 562.

[65] It is noted that despite this characterization, Respondent's Pain Management Agreement with L.M. states that if she breaks the agreement, ''my doctor will taper off the medicine over a period of several days, as necessary to avoid withdrawal symptoms.'' *See e.g.,* GX 175, at 2. Respondent's own Pain Management Agreement appears to dictate a much more specific and shorter period of prescription for discharged patients than what she prescribed for L.M. Although I am not sustaining an allegation regarding this prescription on whether the weaning prescription was appropriate, but instead on a lack of documentation, Respondent's Pain Management Agreement supports Dr. Kaufman's testimony that in order to meet the applicable standard of care, the prescription should have contained a weaning schedule or instructions to ''taper off the medicine.''

[66] This finding is further supported by the regulation's mandate to ''document the plan'' after a breach of the pain management agreement, which was in effect at the time of this prescription. N.J. Admin. Code § 13:35–7.6(f)(5) (West 2020). Even though Respondent documented the discharge, she did not explain the weaning prescription in any way and she provided no instructions to the patient. *See* GX 174 (prescription for 90 Percocet to L.M. on May 24, 2017).

[67] The OSC alleged a total of six inconsistent urine screens for M.W., but the Government did not present evidence about three of these dates through testimony and additionally did not include them in the Prehearing statement or in the Posthearing Brief; and therefore, the ALJ disregarded the inconsistent urine screens on June 1, 2015, November 3, 2015, and April 28, 2017. OSC, at 4; Govt Posthearing, at 11–12; RD, at 90; GX 235; GX 259, ar 116, 154, 158. Although I believe that the record evidence establishes that two of the screens were inconsistent and therefore required documented counseling that did not occur, I will not include them in my findings, because they appear to have been dropped by the Government and I do not find them necessary to my ultimate finding in this case.

RD, at 92–94. In this time period, S.W. submitted a total of eighteen urine samples for screening. RD, at 94–96.

Patient S.W.'s urine tested positive for alcohol metabolites on March 30, May 25, June 22, July 20, and August 23, 2016. RD, at 95–96 (citing GX 288, 293, 296, 299, 302; Stip. 13(a), 13(b), 13(c), 13(d), 13(e)). The patients' records for the prescriptions issued on the visit following the results of these urine screens did not document any specific counseling with regard alcohol.[68] RD, at 93 (citing GX 289, 291, 294, 297, 300, 303). Therefore, I find that the prescriptions for controlled substances issued on April 27, 2016;[69] June 22, 2016; July 20, 2016;August 24, 2016; and September 21, 2016, were not issued within the usual course of practice of medicine and did not meet the applicable standard of care for New Jersey because there was no documented counseling regarding the patient's use of alcohol in her records, nor other explanation of the positive screens. RD, at 96–99, 135–137.

On April 5, 2017, S.W.'s urine screen tested positive for fentanyl. *Id.* at 95 (citing GX 319; Stip. 13(f)). Dr. Kaufman testified that the prescription Respondent issued on May 3, 2017, after the positive fentanyl urine screen did not meet the applicable standard of care in New Jersey and was issued outside the usual course of the professional practice of medicine in New Jersey, because Respondent did not address the fentanyl with S.W. Tr. 249. Respondent testified that S.W. had a history of breast cancer[70] and had told her that the fentanyl was the result of a port being inserted for chemotherapy. RD, at 99 (citing tr. 849). However, the patient records do not reflect this discussion, nor any counseling regarding the fentanyl. *Id.* (citing GX 320, 321). Therefore, the ALJ found, and I agree, that the prescription issued on May 3, 2017, did not meet the applicable standard of care and was issued outside the usual course of the professional practice in New Jersey. *Id.* at 138.

In sum, I find that the record evidence demonstrates that Respondent issued twenty-three prescriptions for controlled substances beneath the applicable standard of care and outside the usual course of the professional practice in New Jersey (five occasions to UC, four occasions to A.P., two occasions to J.C., three occasions to L.M., three occasions to M.W., and six occasions to S.W.). Additionally, I find that the Government has presented substantial evidence that Respondent: failed to conduct a physical examination of the UC in violation of N.J. Admin. Code 13:35–7.1A, and failed to document the discussion of the plan and assess the risk of abuse, addiction or diversion after inconsistent urine screens in violation of N.J. Admin. Code § 13:35–7.6(e) and (f), as further explained in *infra* III(A)(1)(b) for the following prescriptions issued after the regulation's effective date of March 1, 2017: July 25, 2017, to J.C.; February 8, 2018, to A.P.; May 24, 2017, to L.M.; August 25, 2017, to M.W.; and April 5, 2017, to S.W. Additionally, four of these prescriptions violated N.J. Stat. Ann. § 24:21–15.2, which became effective May 16, 2017.

III. Discussion

A. Allegation That Respondent's Registration Is Inconsistent With the Public Interest

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). In the case of a ''practitioner,'' defined in 21 U.S.C. 802(21) to include a ''physician,'' Congress directed the Attorney General to consider the following factors in making the public interest determination:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing . . . controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the . . . 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 15,227, 15,230 (2003).

According to Agency decisions, I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether'' to revoke a registration. *Id.; see also Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016); *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *U.S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482. ''In short, . . . 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; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

Under DEA's regulation, ''[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the

[68] Respondent testified that she was told by a lab that a patient's diabetes could cause a urine screen to be positive for alcohol, and SW was diabetic. Tr. 851, 927. Dr. Kaufman agreed that diabetes may cause a positive alcohol screen, but ''she has to document that there's an average urine screen. It's shown that it's the metabolites of alcohol, and there's a comment that given the light of the patient's diabetes, one would expect a positive urine screen for alcohol[ ].'' Tr. 463. Therefore, despite the possible explanation of why alcohol might have been present, I find that these prescriptions were issued beneath the applicable standard of care, because Respondent did not document her counseling regarding the alcohol in the urine screens or her rationale for not counseling.

[69] The ALJ did not sustain the allegations related to the prescriptions on April 27, 2016, June 22, 2016, July 20, 2016, due to the fact that Dr. Kaufman had testified that the applicable standard of care required the practitioner to discharge a patient who has had alcohol counseling three times and continues to consume alcohol while taking opioids. RD, at 136. As explained herein, I agree with the ALJ that Dr. Kaufman's testimony was confusing on the issue of when to cease prescriptions in the face of an alcohol test; however, I find that Dr. Kaufman also credibly testified that the applicable standard of care in New Jersey required that the Respondent counsel the patient about the alcohol use on each occasion and document that counseling, and there is no such documentation; therefore, I disagree with the ALJ and sustain violations on these dates. *See* Tr. 212.

[70] Respondent argued that S.W.'s records reflect that she had a history of breast cancer and that she was actively being treated for breast cancer because they noted that she was receiving ''Herceptin IV once a week.'' Tr. 630. Therefore, Respondent argued that it was reasonable given her history and ongoing treatment to continue prescribing after the fentanyl. Dr. Kaufman testified that he did not see any documentation in the record explaining the rationale for prescribing and stated, ''It all goes to the crux of the matter. If it's not written here, how can I assume all of that, what you just said, took place? I can't.'' *Id.* at 632. I agree with Dr. Kaufman that the applicable standard of care and State regulation in effect at this time in New Jersey required documentation. *See infra* III(A)(1)(b).

requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.'' 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, the Government's evidence in support of its *prima facie* case is confined to Factors Two and Four.[71] I find that the Government's evidence with respect to Two and Four satisfies its *prima facie* burden of showing that Respondent's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). I further find that Respondent failed to produce sufficient evidence to rebut the Government's *prima facie* case.

1. Factors Two and/or Four—The Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

(a) Allegation That Respondent Issued Prescriptions for Controlled Substances Outside the Usual Course of the Professional Practice

According to the CSA's implementing regulations, a lawful prescription for controlled substances 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, 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).

Respondent engaged a skillful attorney to defend herself against the allegations. I read and analyzed every aspect of Respondent's defense including all of the evidence she put in the record. Respondent's arguments regarding the allegations are not persuasive.

I acknowledge the complexity of this case. The OSC/ISO contained errors, what appeared to be a very adversarial hearing led to confusion relating to testimony on both sides, and the ALJ's statements in the lengthy RD were at times inconsistent with each other.[72] Because of the complexity of this case, I have parsed out only the allegations against that were clearly presented. The end result remains that Respondent issued numerous prescriptions beneath the applicable standard of care and outside of the usual course of the professional practice in New Jersey. 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). In fact, in this case it seems that two out of the six patients presenting were successful in purposefully exploiting Respondent's carelessness (the UC and L.M.).

Respondent contended that the OSC alleged over 150 unlawful prescriptions and the Government only presented evidence about twenty-six and highlights the ALJ's characterization of the OSC as ''error-filled and overzealous.'' [73] Resp Exceptions, at 1. She further alleged that ''[i]t effectively destroyed [r]espondent's practice built up over ten years.'' *Id.* The OSC alleged that Respondent continued to prescribe after she had not documented the resolutions of a multitude of red flags in violation of the applicable standard of care in, and state law of, New Jersey and therefore that every subsequent prescription issued after the first violation to each patient was issued beneath the applicable standard of care and outside the usual course of practice in New Jersey.[74] Although the Government did not litigate the broader allegations that subsequent prescriptions were also in violation, in actuality the majority of the underlying facts alleged in the OSC were, in fact, sustained. I have sustained a few more violations than the ALJ based on the reasons stated herein, but it is truly not the mere number of violations that tip the public interest against Respondent.

Respondent additionally contended that the number of alleged violations only represents a small subset of the 2,800 patient visits that DEA reviewed. *See* Resp Posthearing, at 2. Respondent argued that she has a very busy practice and that the Government presented allegations in only a subset of the prescriptions she wrote, but the violations I have found demonstrate that she repeatedly violated the applicable standard of care and state law and that her conduct was not an isolated occurrence, but occurred with multiple patients and in multiple contexts over a period of years. *See Wesley Pope, M.D.,* 82 FR 42,961, 42,986 (2017).

The Respondent asserted that no one ''died or overdosed or diverted any medication.'' Resp Posthearing, at 1. She does not, however, cite legal authority for the proposition that I must find death, an overdose or controlled substance diversion before I may suspend or revoke a registration. I agree with the ALJ that a decision of revocation does not need to be based on specific evidence of death or overdose. *See* RD, at 141. As the ALJ noted, Agency decisions have found that ''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 prescriptions without complying with her obligations under the CSA and New Jersey law. *See George Mathew, M.D.,* 75 FR 66,138, 66,148 (2010)).

Respondent further argued that the UC failed in obtaining opiates without

[71] I agree with the ALJ that Factors One and Three do not weigh for or against revocation in this case, nor does Factor Five weigh in favor of revocation. RD, at 146. Without referencing Factor One, Respondent mentions that the State of New Jersey has not brought any action against her state license. Resp Posthearing, at 1. However, Agency decisions have long found that in considering Factor One, a state entity's inactions does not weigh for or against revocation. *See Ajay S. Ahuja, M.D.,* 84 FR 5479, 5490 (2019) (finding that ''where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation.'')

[72] *See, e.g.,* RD, at 155 (stating that if Respondent had violated New Jersey law, her ''conduct would have been far more egregious than it actually was); *but c.f.,* RD, at 101, n.49 (''even if N.J. Admin. Code § 13.35–7.1A were considered, such consideration would not change my recommended sanction in this Recommended Decision.'').

[73] I disagree with this characterization of the OSC/ISO. Due to the ALJ's perceived errors in the OSC/ISO, the ALJ also made a statement that was misleading and incorrect. He stated, ''All of these allegations painted a picture of a practitioner whose actions were inconsistent with the public interest. All of those allegations were wrong!'' RD, at 155. In making this statement, the ALJ differentiated between the number of violations presented at hearing and a number that was not quantified in the OSC; incorrectly found that DEA did not prove violations of New Jersey law as alleged in the OSC; differentiated between alcohol and alcohol metabolites, which even Respondent admits is inconsequential to the requirement to counsel about alcohol risks; and highlighted one instance of an incorrect date in the OSC for a negative urine screen (however, the Government omitted two other negative urine screens for this patient that were never addressed and likely would have been found to be violations). RD, at 154–155; *see supra* notes 54, 55. The OSC did contain errors, as described throughout this decision, but several of the instances that the ALJ included here were incorrect and not as egregious as they seemed, and the errors that were made cannot justify a lesser sanction for someone who has not demonstrated that she can be entrusted with a DEA registration. *See infra* note 86.

[74] The ALJ characterized this as over one hundred and fifty prescriptions, but the OSC did not quantify how many prescriptions it was purporting to encompass.

any ailment, because the ''agent was only able to obtain a minimal prescription of a low-dose opiate after presenting an MRI report demonstrating disease.'' Resp Posthearing, at 2. Respondent did require that the UC obtain a clearer MRI before prescribing her controlled substances, she did recommend alternative therapies, she did conduct urine screens, but she also never conducted a physical examination of the UC required by law.[75] Dr. Kaufman credibly testified that Respondent's opioid prescriptions to the UC were beneath the applicable standard of care and outside of the usual course of the professional practice in the State of New Jersey. As discussed below, the New Jersey regulations concur. It is possible that had Respondent required the new MRI and conducted a physical examination as required by law, in order to make her diagnosis, the investigation might have ceased. However, she did not conduct the requisite physical examination. Therefore, I cannot credit her efforts to characterize herself as a victim or attempts to compare this investigation to a ''second Katrina,'' when she was clearly responsible for an undocumented decision to not conduct the physical examination required by New Jersey. Resp Exceptions, at 1 (quoting tr. 789).

I found Respondent's credibility to be dubious and her counseling on the record to be insufficient, but the record was clear that, whether or not Respondent actually counseled patients with inconsistent urine screens or alcohol metabolites, she did not adequately document that counseling to demonstrate that she was actively resolving the issues. The ALJ cited to numerous DEA cases that demonstrate that ''requiring patients to take a drug test serves little purpose, if any, if the registrant ignores the test results.'' RD, at 112 (citing *U.S.* v. *Moore,* 423 U.S. 122, 142–143 (1975); *see also Dreszer, M.D.,* 76 FR at 19,388.)[76] Respondent argued that the ''caselaw cited by the ALJ in support of the documentation requirement seems to stand for the proposition that the documentation is needed to demonstrate that an act occurred, not that the documentation is a prerequisite for the proper practice of medicine.'' Resp Exceptions, at 24 (citing *Gonzales* v. *Oregon,* 546 U.S. 243, 270 (2006)). The cases to which the ALJ cited were decided based on expert testimony and state standards regarding the applicable standard of care and were not, as Respondent implies, medical judgments of the DEA. In this case, the applicable standard of care requiring documentation of the inconsistent urine screens was established by New Jersey laws that have explicitly addressed his issue and credible expert testimony. In fact, in exercising my authority under the CSA, I am instructed to consider ''the registrant's compliance with state and local drug laws.'' *Gonzales* v. *Oregon,* 546 U.S. 243, at 270 (citing 21 U.S.C. 823(f)(4)). Furthermore, 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 she prescribed a controlled substance—adequate documentation is critical to that assessment.

Respondent paints herself as an ''appropriate steward of her controlled-substance license.'' Resp Posthearing, at 2. Further, she argued that ''with her lack of venality and her cautious approach to her practice, it is submitted that [R]espondent is exactly the kind of practitioner who should be encouraged.'' *Id.* at 58. I disagree. Respondent's practice incorporated some safeguards to prevent the diversion of opioids, such as, monthly urine screens, diagnostic testing, and recommending alternative treatments, but the safeguards were not fully implemented in a meaningful way, because she never documented their resolution, if they were in fact resolved. In balancing the public interest, I weigh in Respondent's favor that the record evidence shows that she attempted to implement controls, such as monthly urine screens to prevent diversion. However, the record contains numerous instances where these controls fell short and lacked substance. When she continued to prescribe to Patient L.M. in the face of a multitude of inconsistent urine screens showing three tests for Suboxone in a row, fentanyl, and finally heroin, her justifications were inconsistent and not credible and they were not otherwise documented. *See supra* II(F)(5). When she prescribed to the UC, she claimed that she was basing the five prescriptions on the results of the MRI in lieu of a physical examination, but her diagnosis was inconsistent and the transcript of the recorded video, which shows that she could not appear to recall or find the MRI on some of the subsequent visits. *See supra* II(F)(1). Partially implementing safeguards against diversion is not the same as actually implementing them and is not an excuse for prescribing controlled substances beneath the applicable standard of care and outside the usual course of the professional practice. I therefore find that Factors Two and Four weigh in favor of revocation.

(b) Allegations of Violation of Federal and New Jersey Law

I find that in issuing twenty-three prescriptions beneath the applicable standard of care and outside the usual course of the professional practice in New Jersey, Respondent violated 21 CFR 1306.04(a).

i. New Jersey Administrative Code § 13:35–7.1A

I also find that the Government has proven by substantial evidence that Respondent's failure to conduct an adequate physical examination of the UC constitutes a violation of N.J. Admin. Code § 13:35–7.1A (West 2020) (effective September 15, 2003) (practitioners shall not issue prescriptions ''without first having conducted an examination, which shall be appropriately documented in the patient record'' to include ''an appropriate history and physical examination.''). Respondent characterizes the regulation to require an ''appropriate physical examination,'' but in fact, the regulation requires ''an appropriate history'' and ''physical

[75] I note that this Agency has consistently relied on expert testimony stating that a component of an adequate physical examination is palpation. *See, e.g., Garrett Howard Smith, M.D.,* 83 FR 18,882 (2018); *Randall L. Wolff, M.D.,* 77 FR 5106 (2012). N.J. Admin. Code § 13:35–7.1A (West 2020); Govt Supp Prehearing, at 4.

[76] Agency decisions relying on expert testimony have found that documenting the results of inconsistent urine screens is part of the applicable standard of care. In *Jacobo Dreszer, M.D.,* a case arising in Florida, inconsistent urine screens not only ''should have inspired additional diligence or inquiry on the part of the [r]espondent,'' but they should have also ''raised a sufficient suspicion of diversion to merit further inquiry by the registrant reflected in the patient file.'' 76 FR at 19,394; *see also Cynthia Cadet, M.D.,* 76 FR 19,450, 19,457 (2011) (noting the patient's urine screen produced abnormal results and the respondent ''made no effort to resolve the conflict as best as can be divined from the patient file''). Even though these Agency decisions are not essential or controlling in determining the standard of care in New Jersey that applies to this case, the fact that other medical experts in other states have testified regarding the importance of documenting inconsistent urine screens to their applicable standard of care and that DEA has long highlighted the importance of this aspect of the standard of care in those states to maintaining registrations under the CSA lends further support to the findings herein.

examination.'' Resp Posthearing, at 10. She did not support a reading in New Jersey law that re-arranges the clear order of the regulation's provisions.[77] Even if the word ''appropriate'' in the regulation were to apply only to the physical examination, any practitioner discretion [78] would still be bound by the objective, applicable standard of care in New Jersey, which, as clearly established by Dr. Kaufman, Respondent's treatment of the UC fell below. Additionally, Respondent did not adequately document her justification for why a physical examination was inappropriate or unnecessary under the circumstances. I find that Respondent violated the New Jersey regulation when she prescribed a controlled substance to the UC without having performed an appropriate physical examination.

Respondent further argued both that the patient's MRI gave her a diagnosis and that she had conducted enough of an examination by observing the patient ''to derive a proper etiology of a patient's subjective pain complaints and come up with a plan. . . .'' *Id.* at 10–11. In interpreting the requirements of N.J. Admin. Code § 13:35–7.1A, the New Jersey Office of Administrative Law determined that a physician, who listened to the patient's breathing and ''visually observed her while she was in the examination room'' had ''failed to perform any competent physical examination of her back or spine,'' the place of the patient's complaint. *In the Matter of the Suspension or Revocation of the License of John G. Costino, Jr., D.O. to Practice Medicine and Surgery in New Jersey,* 2009 WL 1396180, at 5. (N.J. Adm.) (May 14, 2009). Respondent's observation of the UC was not a ''competent physical examination'' of the place of the patient's complaint under New Jersey law, her ''diagnosis'' was undercut by her own recordkeeping and statements, and therefore, I find that her treatment of the UC violated this New Jersey regulation. *See supra* (II)(F)(1).

ii. New Jersey Administrative Code § 13:35–7.6(f)(2), (5)

I further find that Respondent violated N.J. Admin. Code § 13:35–7.6(f)(2) and (5) for five prescriptions issued after its effective date of March 1, 2017, where the patients' records demonstrate no documentation of the resolution or ''plan'' after breaches to the pain management agreement due to patients not taking controlled substances as prescribed and no documented assessment of their risk of dependence before issuing additional prescriptions.[79]

Respondent argued that she complied with the requirement to document a ''plan,'' because of what she described as her ''decision-tree analysis'' based on Dr. Gutheil's testimony that the end result shows the judgment that goes before it. Resp Posthearing, at 20 (citing Tr. 1220). ''For [Respondent], whenever there was an inconsistent urine reported, but a prescription was issued, it indicated to her that appropriate counseling was done and all safety concerns were resolved.'' [80] *Id.* (citing tr. 1024–1025, 1027). She further argued that the requirement to document the ''plan'' does not include the counseling or the discussion or the reasons for the breach. *Id.* at 18–19. Respondent offered no New Jersey caselaw, valid regulatory interpretations, or expert testimony related to what constitutes a plan in the context of this regulation under the applicable standard of care and the usual course of the professional practice to support this reading, and legal analysis of the regulation's purpose and history do not support this limited reading.

The plain meaning of the term ''plan'' cannot be, as Respondent suggests, merely identifying the breach and documenting the end result after a discussion. Respondent's own testimony demonstrates why it cannot. With regard to Patient L.M., who tested positive three times in a row for un-prescribed Suboxone, Respondent could not remember why she had not cut L.M.'s dosage even though she testified that after the third positive test, she realized that the ''counseling wasn't successful.'' Tr. 1092–95. The unchanged prescriptions following these visits could not be adequate documentation of a plan to address counseling about a breach of her pain management agreement that Respondent herself knew at that point was not being successful, because Respondent cannot remember why she issued the full prescription or why she resolved the unsuccessful counseling in that manner.[81]

Furthermore, in other sections of the regulation, the State of New Jersey used very different terminology. For example, Section (d) states, ''The practitioner shall include a note in the patient record that the required discussion(s) took place.'' N.J. Admin. Code 13:35–76(d). As discussed earlier, this provision requires that the practitioner note the fact that the discussions took place. The inclusion of the word ''plan'' in the Section at issue indicates that the regulations require more documentation than only a conclusory assertion.

[77] Respondent argued that N.J.S.A. 24:21–15.2 requires a physical exam prior to an initial opioid prescription ''as appropriate.'' Resp Exceptions, at 8. Respondent noted that this provision was not in effect during the treatment in question, but that it ''does give insight into the State's standards.'' *Id.* at n.9. I agree with the Respondent that the New Jersey statutes and regulations give insight into the standard of care in New Jersey, which is one of the reasons why I am including them herein as evidence of the applicable standard of care as contradicting Dr. Epstein's testimony. Although not controlling law on this issue, this statute is not explicit about what the term ''appropriate'' means; however, its implementing regulation states that a practitioner must ''conduct a physical examination appropriate to the practitioner's specialty, including an assessment of physical and psychological function, and an evaluation of underlying or coexisting diseases or conditions.'' N.J. Admin. Code § 13:35–7.6(b)(2) (West 2020). From the regulation, it appears that the term ''appropriate'' in the statute, as interpreted by the New Jersey Attorney General refers to the practitioner's specialty, which would correlate directly to the patient's medical condition, and not to the practitioner's discretion. Further, as noted, Dr. Kaufman credibly testified that Respondent's examination of the UC was not adequate under the standard of care in New Jersey.

[78] To further demonstrate this discretion, Respondent cites to the exceptions to the examination requirement in N.J. Admin. Code § 13:35–7.1A(b) arguing that they list ''circumstances all relate[d] to, other than emergencies, those situations where a patient already has a *diagnosis* for their pain.'' Resp Posthearing, at 8 n.2. In fact, the provisions unrelated to emergencies are either because the physician is assuming the care of the patient for another practitioner who has performed a physical (b)(2) and (b)(5); or for ''an established patient who, based on sound medical practice, the physician believes does not require a new examination before issuing a new prescription.'' N.J. Admin. Code § 13:35–7.1A(b)(4) (West 2020). As the ALJ notes, there is no evidence on the record to support Dr. Epstein's claim that the UC was Respondent's ''established patient'' at the time of her second visit. RD, at 15. Additionally, even if she were considered an established patient, the term ''new'' examination necessarily implies that there was a previous examination, and there was not.

[79] I am considering Section 13:35–7.6(f)(2), because although there was limited specific discussion of this Section in the record, together Sections (f)(2) and (f)(5) demonstrate the requirement to document the rationale for continuing to prescribe after inconsistent urine screens—whether it is to develop a plan or assess the risk of the individual patient. The finding of violations of these sections individually has not been given any additional weight in my decision to revoke. Dr. Kaufman clearly testified that ''within the State of New Jersey, each time the patient comes in, you're supposed to assess the patient, to make sure that, A, that they're taking it. B, that it is efficacious, are there any side effects? And then, make a justification as to continuation of therapy.'' Tr. 201–202.

[80] Dr. Gutheil testified at most that documentation of the result ''does minimally'' document what occurred in terms of the physician-patient interaction. Tr. 1220. However, in no way did Dr. Gutheil's testimony address the statutory requirement to discuss breaches and document the plan and how a decision tree analysis would meet that requirement.

[81] I am using this as an example to demonstrate why the prescription alone cannot demonstrate the ''plan.'' The regulation was not in effect until the prescription issued after Patient L.M. tested positive for heroin and was discharged in April of 2017.

In interpreting the meaning of a regulation, ''agencies normally address problems in a detailed manner and can speak through a variety of means, including regulations, preambles, interpretive statements, and responses to comments. . . .'' *Hillsborough County, Fla.* v. *Automated Medical Labs., Inc.* 471 U.S. 707, 718 (1985). The New Jersey regulation requiring a ''plan'' was adopted through emergency amendments ''because of the imminent peril created by the epidemic of prescription opioid and heroin abuse in New Jersey.'' New Jersey Division of Consumer Affairs, Rule Proposal, Volume 49, Issue 6, (March 20, 2017) *available at: https://www.njconsumeraffairs.gov/proposals/pages/03202017-bme-proposal.aspx* (hereinafter, the Preamble).[82] Further, the Preamble to the regulation states that a statute was signed into law—Public Law 2017, c. 28, codified at N.J. Stat. § 24:21–15.2; however because it ''does not become effective until May 16, 2017, the Attorney General has determined that this rulemaking is necessary because the state of New Jersey is confronting a staggering public health crisis brought about by prescription opioid and heroin abuse.'' *Id.* One reason for the public health emergency is ''the prevalence of opioid prescribing.'' *Id.*

There are two affirmative obligations in the regulation that are applicable to this record—''[w]hen controlled dangerous substances are continuously prescribed for management of chronic pain'' [83] (defined as pain continuing for three months), the practitioner shall ''assess the patient prior to issuing each prescription to determine whether the patient is experiencing problems associated with physical and psychological dependence, and document the results of that assessment'' and ''monitor compliance with the pain management agreement . . . and discuss with the patient any breaches that reflect that the patient is not taking the drugs prescribed or is taking drugs, illicit or prescribed by other practitioners or prescribers, and document within the patient record the plan after that discussion.'' N.J. Admin. Code §§ 13:35–7.6(f)(2), (f)(5). The preamble to the regulation states that (f)(2) ''contains an affirmative obligation to assess the patient prior to the issuance of each prescription for a controlled dangerous substance.'' The Preamble, at 7. ''Overall the amendments to this subsection are designed to increase practitioner involvement and vigilance when prescribing for the treatment of chronic pain, and to ensure that the patient record reflects active pain management procedures.'' *Id.*

The Preamble is very clear that the State of New Jersey's purpose in enacting emergency controls on prescribing controlled dangerous substances for chronic pain is to ensure not only vigilance and involvement but that these ''active pain management procedures'' are also reflected in the patient record. Additionally, reading the two paragraphs together, it is apparent that the practitioner must assess the risks before every prescription and where there is a breach to the pain management agreement that demonstrates a potential risk of dependence, the plan and the assessment must be documented. Therefore, I find that five prescriptions with unresolved inconsistent urine screens issued after the effective date of March 1, 2017, violated N.J. Admin. Code § 13:35–7.6(f)(2) and (5).

iii. New Jersey Statute § 24:21–15.2 [84]

In its Posthearing Brief and Exceptions, the Government alleged that ''when issuing prescriptions for opioids practitioners must determine 'that the issuance of the subsequent prescription does not present an undue risk of abuse, addiction or diversion and [must] document[ ] that determination.' '' Govt Posthearing, at 15–16 (citing N.J. Stat. Ann. § 24:21–15.2(c)(3)). The Section of the statute that the Government cited appears to apply only when issuing a subsequent prescription ''no less than four days after issuing the initial prescription.'' N.J. Stat. Ann. § 24:21–15.2(c). It is not clear from the plain language of the subsection that the risk assessment would be required for *every* subsequent prescription could also be in conflict with subsection (f)(2), which requires that *after three months* of prescribing a Schedule II controlled dangerous substance or any opioid drug for chronic pain the physician must ''assess the patient prior to every renewal to determine whether the patient is experiencing problems associated with physical and psychological dependence and document the results of that assessment.'' N.J. Stat. Ann. § 24:21–15.2(f)(2). Despite the Government's error in citing to subsection (c) in its Posthearing filings, it did not so limit itself in its Supplemental Prehearing Statement or Posthearing Brief. The Supplemental Prehearing Statement stated that N.J. Stat. Ann. § 24:21–15.2 requires ''that a doctor prescribing opioids enters into a pain management agreement with patients; and that patients receiving opioids are monitored for compliance with the pain management through various measures such as drug screens'' and further that a physician's compliance with the statute ''must be documented in a patient's medical records.'' Govt Supp Prehearing, at 4. Although not specifically noted, the Government was clearly implicating Sections N.J. Stat. Ann. § 24:21–15.2 Sections (e) and (f) pertaining to chronic pain, because the pain management agreement is not required under the subsequent prescription in Section (c) and Respondent and the Government presented arguments during the hearing implicating these sections; therefore, I find that, despite the Government's Posthearing briefings, Respondent was on adequate notice of the allegations of these violations and they are appropriately considered.

Respondent argued that the statute does not specify the requirement to document noncompliance with the pain management agreement. *See* Resp Supp Prehearing, at 3. Respondent further argued that, because the statute was enacted after the regulation and the documentation was ''intentionally absent'' in the statute, a narrow reading of the term ''plan'' in the regulation is more appropriate, because if New Jersey had intended a broader interpretation, it would have required this by statute. Resp Posthearing, at 19. The history of the statute and the regulation refutes Respondent's contention. P.L. 2017, c. 28 was signed into law on February 15, 2017, prior to the emergency adoption of N.J. Admin. Code § 13:35–7.6 on March 1, 2017. The stated purpose of the emergency regulation was because ''P.L. 2017, c.28, does not become effective until May 16, 2017.'' Preamble,

[82] The online version of the Preamble does not contain pagination; therefore, the page references are based on a printed copy of the online document.

[83] '' 'Chronic pain' means pain that persists for three or more consecutive months and after reasonable medical efforts have been made to relieve the pain or its cause, it continues, either continuously or episodically.'' N.J. Admin. Code 13:35–7.6(a) (West 2020). Due to the fact that the patients in this case were prescribed opioids for more than three months prior to this regulation, I believe that they fall under this definition.

[84] Regarding N.J. Stat. Ann. § 24:21–15.2, the ALJ found that the statute ''by its terms, applies to 'initial prescriptions' and ''the Government presented no evidence to show that the prescription [Respondent] issued to [UC] was her first prescription for an opioid.'' RD, at 111 (citing N.J. Stat. § 24:21–15.2(b)). The statute also was not in existence at the time that the alleged violations related to UC had occurred, as the relevant portions came into effect on May 16, 2017, and therefore I am disregarding his conclusions on that issue.

at 2. The Attorney General of New Jersey believed that the ''staggering public health crisis brought about by prescription opioid and heroin abuse'' could not wait for even another three months to become effective. *Id.* Further, because the ''standards set forth in this rulemaking will provide a basis to seek emergent action to suspend or limit licenses pending a plenary hearing, pursuant to N.J.S.A. 45:1–22, and/or for disciplinary sanctions pursuant to N.J.S.A. 45:1–21,'' I find that New Jersey intended that the regulatory violations found above also constitute statutory violations. *Id.*

Therefore, I find sufficient evidence to sustain violations of N.J. Stat. Ann. § 24:21–15.2 for the three prescriptions occurring after it was effective on May 16, 2017. I further find that these provisions support Dr. Kaufman's testimony regarding the importance under the New Jersey standard of care of documenting not only the fact that counseling occurred, but also the resolution of such counseling.

The laws that New Jersey has implemented clearly demonstrate the extent to which the applicable standard of care in New Jersey relies on, not just checking for compliance with the pain management agreement, but that breaches, such as inconsistent urine screens are discussed and ''the plan after that discussion'' is documented in the patient record. N.J. Admin. Code § 13:35–7.6(f)(5) (West 2020). These laws require more than lip service to safeguards, but actual rational, thoughtfulness on the part of the practitioner in making the decision to reissue a prescription to someone who is presenting red flags or danger AND the memorialization of that decision. To preserve the value of New Jersey law, I cannot agree with the ALJ here that this is ''not the sort of recordkeeping violation that would defeat the purpose of the Controlled Substances Act.'' RD, at 150.[85] Documentation of a practitioner's decision-making is essential to the practitioner's accountability for that decision—it ensures that the practitioner is actually processing the information in front of her and applying it to her care of the patient and marking it with permanence.

(c) Summary of Factors Two and Four and Imminent Danger

As found above, the Government's case establishes by substantial evidence that Respondent issued controlled substance prescriptions outside the usual course of the professional practice. I, therefore, conclude that Respondent engaged in misconduct which supports the revocation of her registration. *See Wesley Pope,* 82 FR 14,944, 14,985 (2017).

For purposes of the imminent danger inquiry, my findings also 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 issued controlled substance prescriptions outside the usual course of the professional practice establishes that there was ''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 registrations. *Id.; see, e.g.,* tr. 213, 482 (the opinion of the Government's expert, Dr. Kaufman, that mixing alcohol and opioids could result in death); tr. 1494 (opinion of Dr. Epstein that ''people who use fentanyl as an abuse drug die.'').[86] In particular, Respondent did not dismiss Patient L.M. after she had tested positive for fentanyl, Suboxone, and heroin, while still testing positive for prescribed oxycodone several times, and she did not document any explanation or discussions with Patient L.M. regarding breaches of her pain management agreement, which is particularly egregious in the face of the danger that her urine samples demonstrated. Although Respondent presented evidence to mitigate the egregiousness of her prescribing to patient SW, she was required to maintain adequate records describing the mitigating circumstances under the applicable standard of care in New Jersey and by New Jersey law; and therefore, the Government could not have known about these mitigations at the time of issuing the ISO. Although I agree that the OSC/ISO contained errors,[87] I do not agree with the ALJ's statement that it was overzealous.[88] *See* RD, at 154. At the time the Government issued the OSC/ISO, the Government had clear evidence of violations of law through an undercover who had been unlawfully prescribed controlled substances and records that appeared to demonstrate a practitioner who was prescribing with no explanation to individuals whose urine screens were demonstrating dangerous combinations of unprescribed controlled substances and alcohol or consistently showing no evidence of the controlled substances that she had prescribed.

IV. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration is inconsistent with the public interest due to her violations pertaining to controlled substance prescribing and non-compliance with federal and State law, the burden shifts to the Respondent to show why she can be entrusted with a new registration. *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018) (collecting cases).

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. at 259. 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

[85] 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, that ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse.'' *Gonzales* v. *Oregon,* 546 U.S. at 274.

[86] Although Dr. Epstein's testimony about fentanyl was aimed at concluding that L.M.'s multiple urine tests showing fentanyl must have been incorrect or a result of surgery, the evidence in the record demonstrates that L.M. was, in fact, also abusing heroin, so it seems likely that she was abusing fentanyl that was not legitimately prescribed, thus this danger that he is describing is applicable in this case.

[87] It is noted that although the OSC included some errors, such as that it alleged that on May 5, 2017, A.P.'s urine screen was negative for prescribed controlled substances, it also contained errors that omitted evidence which would have likely resulted in additional findings of violations, so the fact that the OSC included errors also benefitted Respondent. *See, e.g., supra* notes 49, 52, 55, 59, 60, 66. Additionally, I would not have altered my decision on the Immediate Suspension Order due to these errors. There was enough evidence without them to justify the suspension of Respondent's registration.

[88] In making this statement, the ALJ highlighted the fact that the OSC argued that all prescriptions after the date of the first prescription were unlawful, which would have encompassed over 150 unlawful prescriptions. RD, at 154. Although I agree with the ALJ on the legal matter that the Government did not prove this allegation, as stated previously, the OSC did not quantify how many prescriptions it was attempting to encompass; therefore, the impact of that number was not as strong as the ALJ implies.

argument Respondent submitted to determine whether or not she has presented ''sufficient mitigating evidence to assure the Administrator that [she] 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. Kennnedy, 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).

In evaluating the degree of a respondent's acceptance of responsibility required to entrust her with a registration, in *Mohammed Asgar, M.D.,* 83 FR 29,569, 29,572 (2018), the Agency looked for ''unequivocal acceptance of responsibility when a respondent has committed knowing or intentional misconduct.'' *Id.* (citing *Lon F. Alexander, M.D.,* 82 FR 49,704, 49,728 (2017)). The ALJ found, and I agree, that ''Respondent has not accepted responsibility, other than to concede that she 'should have written more.' '' RD, at 152 (citing tr. 1071). Respondent's assertion that she ''should have written more'' barely scrapes the surface of these issues, and seems to be an attempt to minimize the severity of her actions by so lightly characterizing a substantive documentation requirement. Tr. 1071; *see Jeffrey Stein, M.D.,* 84 FR 46,968, 46,973 (2019) (finding that a registrant's minimization in describing his crime weighed against a finding of acceptance of responsibility). Respondent argued that she did accept responsibility for the prescriptions to the UC, when she stated that ''yes, she wrote it, she wrote the scripts.'' Tr. 874; *see* Resp Exceptions, at 33. But when asked whether the prescriptions were issued outside the usual course of the professional practice, she answered no. Tr. 875. Accepting responsibility for writing the prescriptions does not equate to admitting fault. *See Hoxie* v. *Drug Enf't Admin.,* 419 F.3d at 483 (''The DEA properly considers the candor of the physician'' and ''admitting fault'' is an ''important factor[ ] in determining whether the physician's registration should be revoked''). Additionally, Respondent compared the DEA case to her ''second Katrina,'' which ultimately demonstrates that she takes no responsibility for her violations of law, but instead views herself entirely as a victim of forces beyond her control. Tr. 789.

Respondent's mitigating evidence and the Government's mistakes have whittled down or softened some of the violations in this case; however, I see no evidence from Respondent that demonstrates that she will ''prevent the re-occurrence of similar acts.'' *Jeri Hassman, M.D.* 75 FR 8194, 8236 (2010). Acceptance of responsibility is an important part of that demonstration. *Id.* Although the evidence of her struggles with her software system is relatable at a basic level to every human being who has experienced technological frustrations, it again shows a passing of blame and an unwillingness to accept responsibility for a legal requirement and a requirement of the applicable standard of care and the usual course of the professional practice in her field to document her prescribing practices and decisions. Documentation of the discretion that Respondent had been implementing in her prescribing practices in the face of inconsistent urine screens is similar to accepting responsibility for her actions, because it memorializes her decisions with permanence. None of the recordkeeping in the Government's evidence demonstrates the rationale behind her prescribing decisions and she demonstrated through her testimony that her memory is not reliable to fill in the gaps.

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. With regard to specific and general deterrence, it is my responsibility under the CSA to encourage the good practices of preventing diversion that Respondent had implemented, including but not limited to, increasing urine screens to detect abnormalities, requiring an MRI to obtain more information about the source of pain, and encouraging alternative treatments; however, those additional measures are of no value to their stated purpose if the results of the urine screens are ignored. The cavalier attitude with which Respondent treated her documentation responsibilities and the fact that she did not undertake this responsibility with seriousness in any of these instances, weigh against my ability to entrust her with a registration. *See Singh, M.D.,* 81 FR at 8248 (''until . . . [a] Respondent can convincingly show he [or she] accepts the authority of the law and those bodies charged with enforcing it and regulating his [or her] activities, granting [ ] a DEA registration will gravely endanger the public.''). Therefore, I disagree with the ALJ that ''specific and general deterrence do not weigh in favor of revocation in this case.'' RD, at 153. The interests of general deterrence in discouraging practitioners from ignoring their legal obligations and not genuinely complying with important recordkeeping provisions, and the interests of specific deterrence in preventing Respondent from hiding behind rote diversion controls without legitimately attending to and documenting red flags weigh in favor of a sanction of revocation.

Although the ALJ ultimately recommended a sanction short of revocation, I cannot agree, because there is insufficient evidence in the record to demonstrate that Respondent can be entrusted with a registration. *See Leo R. Miller, M.D.,* 53 FR 21,931, 21,932 (1988) (describing revocation as a remedial measure ''based upon the public interest and the necessity to protect the public from individuals who have misused controlled substances or their DEA Certificate of Registration and who have not presented sufficient mitigating evidence to assure the Administrator that they can be trusted with the responsibility carried by such a registration.''). The ALJ's recommended mitigations might have helped Respondent understand better the legal requirements and might have permitted DEA to monitor her progress more easily, but they do not solve the underlying issue of trust.[89] If I did not

[89] In fact, the ALJ does not address the issue of whether I can trust the Respondent at all in his Recommended Decision. Most of the statements in the RD do not demonstrate that I can trust her, such as his qualified finding of her credibility. RD, at 22–24. It seemed from the ALJ's diction and

appropriately consider whether Respondent had accepted responsibility such that I could entrust her with this responsibility, I would be minimizing Registrant's violations of state and federal law, undermining the public interest by not attempting to address those violations, and then placing the burden on the Agency whose trust she broke to monitor her compliance. Although such measures may be appropriate in some cases, here, Respondent has not given me a reason to extend them to her.

Accordingly, I shall order the sanctions the Government requested, as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration BK9710939 issued to Kaniz F. Khan-Jaffery, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Kaniz F. Khan-Jaffery, M.D., to renew or modify this registration, as well as any other applications of Kaniz F. Khan-Jaffery, M.D. for additional registration in New Jersey. This Order is effective August 28, 2020.

Timothy J. Shea,

Acting Administrator.

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punctuation that it was his frustration with the Government's case that led him to recommend a sanction less than revocation. *See id.* at 155. However, I cannot exclude from a final determination on this case consideration of the issue of trust in the face of violations, even where there are fewer violations found than initially alleged.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17–41]

Hamada Makarita, D.D.S.; Denial of Application

I. Introduction

On June 29, 2017, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Hamada Makarita, D.D.S. (hereinafter, Applicant), of McLean, Virginia. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause (hereinafter, OSC)), at 1. The OSC proposes the denial of Applicant's application for a DEA certificate of registration (hereinafter, registration) alleging that he does not have authority to handle Schedule II to IV controlled substances in Virginia, he has been convicted of felony counts related to controlled substances, and his registration would be inconsistent with the public interest.[1] *Id.* (citing 21 U.S.C. 823(f) and 824(a)).

The substantive grounds at issue in this proceeding, as more specifically alleged in the OSC, include that Applicant, ''[o]n April 12, 2013, . . . [was] convicted of eight felony counts in the United States District Court for the Eastern District of Virginia, Alexandria Division, six of which were related to controlled substances,'' one of which was for health care fraud, and one of which was for aggravated identity theft. OSC, at 2–3 (citing 21 U.S.C. 823(f)(3) and 824(a)(2) and (a)(4)). The OSC also alleges that Applicant ''fail[ed] to accept responsibility for . . . [his] convictions.'' OSC, at 3.

Regarding the allegation that Applicant's registration would be inconsistent with the public interest, the OSC alleges twelve findings of fact by the Virginia Board of Dentistry (hereinafter, VBD) concerning Applicant's prescribing controlled substances without or beyond a legitimate dental purpose. *Id.* at 4–5 (citing 21 U.S.C. 841(a) and 842(a), 21 CFR 1306.04(a), and Virginia Code secs. 54.1–2706, 54.1–3303(A), and 54.1–3408(A)). The OSC also alleges that Applicant ''refused to accept responsibility for . . . [his] unlawful prescriptions.'' OSC, at 5.

The OSC notified Applicant of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 5–6 (citing 21 CFR 1301.43). The OSC also notified Applicant of the opportunity to file a corrective action plan. OSC, at 6 (citing 21 U.S.C. 824(c)(2)(C)).

The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge (hereinafter, ALJ) John J. Mulrooney, II. The parties initially submitted seven stipulations.[2] RD, at 3; ALJX 8, at 1–2 (original).

The hearing in this matter lasted one day and took place in Arlington, Virginia on October 10, 2017. The Chief ALJ filed his RD on January 19, 2018. Neither party filed exceptions to the RD and the time for filing exceptions has expired. Letter of the Chief ALJ to the Acting Administrator, dated Feb. 14, 2018, at 1.

Having examined and considered the record in its entirety, I agree with the Chief ALJ that substantial record evidence establishes Applicant's six federal felony convictions relating to the dispensing of controlled substances, the Fourth Circuit's affirmance of those felony convictions, and Applicant's completion of his appeals of those convictions. I find substantial record evidence of the VBD's finding that Applicant illegally prescribed over 2,700 dosage units of Schedule II through IV controlled substances. I find that Applicant did not unequivocally accept responsibility for all of this proven controlled substance-related wrongdoing. Accordingly, I conclude that granting Applicant's request for a

[1] According to Applicant's request for a hearing, ALJX 2, Applicant's original registration application only concerned Schedule V controlled substances. ALJX 2, at 1. Applicant subsequently revised that application, the hearing request states, to include Schedule II through IV controlled substances. *Id.* ''In light of his inability to prescribe Schedule II through IV substances due to the findings and ruling of the Board of Dentistry of Virginia,'' Applicant's hearing request continues, he ''hereby withdraws his amended request for permission to prescribe Schedule II through IV substances'' and ''now requests only to have authority to prescribe Schedule V substances.'' *Id.; see also* ALJX 8 (Prehearing Ruling dated Aug. 31, 2017), at 2 (Stipulation No. 4), *infra* n.2.

The Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge in this matter (hereinafter, RD) states that Applicant's hearing request was ''timely filed.'' RD, at 2; *see also* Transcript page (hereinafter, Tr.) 5 (noting that Applicant filed a hearing request on July 31, 2017).

[2] In the stipulations, Applicant is referred to as ''Respondent.''

''1. On September 20, 2016, the Respondent filed an application for a DEA COR, Control No. W16093263C, seeking registration as a practitioner in Schedule V with a registered address of 4103 Chain Bridge Road, Suite LL 100, Fairfax, Virginia 22030.

''2. The Respondent currently possesses Dental License number 0401007149 from the Commonwealth of Virginia. His dental license expires on its own terms on March 31, 2018.

''3. The Respondent lacks authority in the Commonwealth of Virginia to handle Schedule II, III, or IV Controlled Substances.

''4. In the Respondent's Request for Hearing, he withdrew a prior request for Schedule II–IV authority.

''5. On April 12, 2013, the Respondent was convicted of eight felony counts in the United States District Court for the Eastern District of Virginia, Alexandria Division.

''6. The Respondent applied for reinstatement of his state dental license in 2016. The Virginia Board of Dentistry made a number of findings on September 22, 2016, regarding the Respondent's treatment of a number of patients.

''7. Following the hearing, the Board reinstated the Respondent's state dental license with conditions on September 22, 2016.''

On September 20, 2017, the parties filed additional Joint Stipulations, ALJX 10, agreeing to the authenticity of four of the seven Government Exhibits (hereinafter, GX) and five Applicant Exhibits (hereinafter, RX). ALJX 10, at 1–2.

Schedule V registration would be ''inconsistent with the public interest.'' [3] I make the following findings.

II. Findings of Fact

A. Applicant's State Dental License and Controlled Substance Authorization

Applicant is licensed as a dentist in the Commonwealth of Virginia. *See, e.g.,* RX 6 (Letter from the Commonwealth of Virginia, Department of Health Professionals to Applicant referencing ''Case No.: 178272—Inspection Report/Records Audit'' dated September 29, 2017), at 1. According to the online records of the Commonwealth of Virginia, of which I take official notice, Applicant's dental license is currently active. It expires on March 31, 2021.[4] Virginia Department of Health Professions License Lookup, *https://dhp.virginiainteractive.org/Lookup/* Index (last visited July 21, 2020).

After Applicant served his sentence and was released from federal custody, the VBD limited Applicant's authorization to issue controlled substance prescriptions to Schedule V. GX 3 (Order Before the Virginia Board of Dentistry In Re Hamada R. Makarita, D.D.S., License Number: 0401–007149, Case Number: 86781, 136371, 143367, 152192, dated, entered, and mailed on September 22, 2016 (hereinafter, VBD Order)), at 11; *see also* Tr. 51. According to the VBD Order, this limitation on Applicant's prescribing and dispensing authority was to last for two years from the date of the VBD Order, September 22, 2016. GX 3, at 12.

B. The Investigation of Applicant

A DEA field investigation of Applicant began because he responded ''yes'' to ''a few liability questions on an application.'' [5] Tr. 15; *see also id.* at 15–17 (describing the internal DEA processes that ensue when an applicant provides a ''no'' answer and a ''yes'' answer to a liability question). Applicant answered ''yes'' to three questions. The first question to which Applicant answered ''yes'' asks, in pertinent part, ''Has the applicant ever been convicted of a crime in connection with controlled substance(s) under state or federal law?'' GX 7, at 3; *see also* Tr. 21–22. Under ''nature of incident'' regarding his ''yes'' answer to the first liability question, Applicant wrote:

> I found out my office manager was using my DEA license to call in rx to herself and friends and I called the FBI and she convinced the FBI agent I was the on [sic] who told her to. This was a lie. The judge said I was responsible for my ploys [sic] actions so I was convicted of conspiracy to distribute narcotics. She said I gave her permission which is not true at all or why would i [sic] have called the authorities and go to a lawyer and fire her?

GX 1, at 2. Concerning ''result,'' in connection with the first liability question, Applicant wrote:

> I voluntarily surrendered my DEA license and also I am applying only for schedule 5 drugs so I can treat my patients with NSAids [sic] for pain and antibiotics. I had my hearing with the board of Dentistry last week and my license was reinstated. It was a mandatory suspension because of the conviction. I will be pressing charges against this office manager again! I only wish to have permission for schedule 5 for now as it is a must to teat [sic] infections etc with antibiotics as well as NSAIDS for pain.

Id.

The second question to which Applicant answered ''yes'' asks, ''Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?'' GX 7, at 3. For ''nature of incident'' regarding his ''yes'' answer to the second liability question, Applicant's submission was the same as his submission for the first liability question. GX 1, at 2. Likewise, Applicant wrote the same ''result'' concerning the second liability question as he wrote for the first liability question. *Id.*

The third question to which Applicant answered ''yes'' asks, ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' GX 7, at 3. Concerning ''nature of incident'' regarding his ''yes'' answer to the third liability question, Applicant wrote:

> Due to conviction, the state dental board had to suspend (not revoke) my license because it is in the statutes. Although they had not hear [sic] day case until last week in full, and once they did and were presented with proofs of who was the culprit, they reinstated my license with no fines at all.

GX 1, at 3. For the ''result'' concerning the third liability question, Response wrote, ''License was suspended April 36, [sic] 2013 and reinstated Sep 15, 2016.'' *Id.*

C. The Felony Criminal Convictions and VBD Findings

According to Government counsel, the ''basis of the Government's *prima facie* case'' is that Applicant was convicted in federal court of dispensing controlled substances in violation of the Controlled Substances Act (hereinafter, CSA) and that the VBD ''found that he committed those unlawful actions.'' [6] Tr. 10. In his opening statement, counsel for Applicant stated that ''[w]e don't deny that . . . [Applicant] was convicted and there are Board findings against him.'' [7] *Id.* at 11. The uncontested criminal convictions and VBD findings are set out in Government Exhibits (hereinafter, GX) 2, 3, and 5, discussed *infra* section II.D.

There is factual agreement among the witnesses on a number of matters. When there is factual disagreement, I apply my credibility determinations and the credibility recommendations of the Chief ALJ.

D. The Government's Case

The Government called one witness, the DEA Diversion Investigator case agent (hereinafter, DI). The

[3] I reviewed, and agree with, the Chief ALJ's pre-hearing, hearing, and post-hearing rulings and orders.

[4] 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 shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Applicant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response shall be filed and served by email on the other party at the email address the party submitted for receipt of communications related to this administrative proceeding, and on the Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

[5] Application liability questions ask about ''past history'' such as a felony criminal conviction, an action against a state license, and an action against a registration. Tr. 15–16.

[6] Government counsel argued in his opening statement that Applicant ''has not accepted responsibility for his actions'' as evidenced by ''his application to the DEA and his pre-hearing statements and his conversations with the original Investigator.'' Tr. 10.

[7] Applicant's Counsel continued by stating that the federal convictions and VBD findings stemmed from Schedule II and III ''related issues,'' that Applicant has ''never been accused of or found guilty of or had any adverse . . . [VBD] findings concerning Schedule . . . [V] substances,'' that Schedule V ''substances typically are not the types of drugs that are sought out by addicts and people of that type, nor are those the types of drugs that lead to great financial wealth or anything of that nature,'' and, therefore, ''given the circumstances and given the work that . . . [Applicant] has done . . . , we believe it is consistent with the public interest to allow him to now dispense Schedule . . . [V] substances.'' Tr. 11–12.

Government's case included seven exhibits, all of which were accepted into the record.[8]

DI's testimony addressed Applicant's application, the process of referring that application for investigation, and her investigation of the application, including her obtaining documents relevant to the application and her communicating with Applicant. *Id.* at 14–33.

DI testified that she had email and telephonic contact with Applicant. *Id.* at 28–33. According to DI, Applicant told her that ''he did want to go before the judge,'' and that the judge told him that ''he was responsible, so he was convicted.'' *Id.* at 31. She testified that Applicant told her that ''he never abused, sold drugs or anything like that'' and that ''he wanted to present his case to the [administrative law] judge and not just apply for Schedule 5, but for 2 through 4 as well.'' *Id.; see also* GX 4 (Feb. 7, 2107 Letter from Applicant amending his September 20, 2016 Registration Application ''to all schedules . . . as opposed to just schedule V''), at 1; GX 6 (Nov. 20, 2016 Email from Applicant to DI stating that ''I have never abused, sold drugs, or anything like that'' and ''I wish . . . also not just [sic] apply for schedule 5 but for all of it''), at 1.

On cross examination, as clarified on redirect, DI recounted her recollection that Applicant admitted, in his application for a DEA registration, to having been criminally convicted.[9] Tr. 34, 42. She testified that she did not find ''any inconsistencies or issues'' about Applicant's background on his application. *Id.* at 34–35. She stated that she did not recall the involvement of a Schedule V controlled substance in Applicant's criminal convictions or in the VBD findings. *Id.* at 35. In her experience, she testified, Schedule II through V controlled substances are diverted by doctors, and ''pill mill-style doctors'' prescribe more Schedule II through IV controlled substances than Schedule V controlled substances. *Id.* at 35–37. She testified that she did not check whether Applicant uses or was ever prescribed a controlled substance, and that she did not recall whether the federal indictment or the VBD charges alleged that Applicant abused a controlled substance.[10] *Id.* at 37–38.

I agree with the Chief ALJ that DI ''presented testimony that was detailed, plausible, internally consistent, and devoid of any indication of any cognizable motive to fabricate. She gave every appearance of an impartial investigator/regulator, was forthcoming and candid in her responses to questions, and her testimony is accepted here as fully credible.'' RD, at 13.

The Government's admitted documentary evidence consists of documents detailing the disposition of the felony criminal charges brought against Applicant, the Circuit Court's affirmance of the charges of which Applicant was convicted, and the VBD's findings of fact, conclusions of law, and Order concerning Applicant's medical license and controlled substance prescribing authority. GX 2, 3, and 5, respectively. The Government also put in the record Applicant's correspondence with DEA and DI related to his registration application and background information to help contextualize that correspondence. GX 1, 4, 6, and 7.

GX 2 consists of six sheets concerning Applicant's eight felony convictions in the Eastern District of Virginia. GX 2 (Judgment, *United States* v. *Makarita,* No. 1:12cr00223–001 (E.D. Va. Apr. 12, 2013) (hereinafter, Eight Felony Conviction Trial)). The first sheet is the ''Judgment in a Criminal Case.'' *Id.* at 1. It shows that Applicant was ''found guilty as to Count(s) 1, 2, 3, 10, 12, 13, 14, and 15 of the Indictment,'' all of which are felonies. *Id.* The second sheet shows that Applicant was sentenced to twenty-five months of imprisonment. *Id.* at 2. The third sheet shows that Applicant was put on supervised release for three years. *Id.* at 3.

The first count listed on the Judgment of the Eight Felony Conviction Trial is conspiracy to distribute and dispense controlled substances in violation of 21 U.S.C. 846. *Id.* at 1. Applicant appealed his conviction on this count arguing that ''there was insufficient evidence to support his conviction . . . because the evidence failed to demonstrate any agreement to illegally distribute controlled substances between him and any other individual.'' 576 F. App'x at 262–63 (GX 5, at 9). According to the Fourth Circuit Conviction Affirmance, however, Applicant's ''conviction for conspiracy is supported by substantial evidence.'' 576 F. App'x at 263 (GX 5, at 9). The Eight Felony Conviction Trial testimony of two of Applicant's former employees, his former office manager and his former dental assistant, ''established that . . . [Applicant] entered into an agreement with each of them to pick up prescriptions in their own names and deliver them to . . . [Applicant], either for him to illicitly deliver to others, or for his own personal use.'' [11] *Id.* In the face of the conflicting testimony of Applicant, ''the jury elected to credit . . . [the two former employees'] testimony'' over Applicant's. *Id.*

[8] The parties agreed to the authenticity of four of the Government's Exhibits. ALJX 10; *see also supra* n.2.

[9] On re-direct, DI clarified that Applicant's application accurately admitted to the existence of criminal convictions, and that she had not addressed the accuracy of Applicant's description of the facts underlying those convictions. Tr. 42.

[10] Regarding whether Applicant abused drugs in Schedules II, III, or IV, the Fourth Circuit's *per curiam* decision upholding Applicant's criminal convictions describes Count 10 as charging Applicant with illegally distributing or dispensing a controlled substance to his former office manager. *United States* v. *Makarita,* 576 F. App'x 252, 256 (4th Cir. 2014) (hereinafter, Fourth Circuit Conviction Affirmance) (GX 5, at 4). The Fourth Circuit Conviction Affirmance describes evidence that Applicant wrote a prescription for ''several boxes of [f]entanyl patches'' for his former office manager to fill and deliver to him, and that Applicant applied one of the patches to his body in the former office manager's presence. *Id.* Also according to the Fourth Circuit Conviction Affirmance, Applicant ''corroborated'' this evidence, testifying that ''I was hoping this was something I could use as a treatment modality to use for any oral pain. That's why I used it on myself. I said, 'I want to see if it helps my back.' '' *Id.*

According to the prosecution's expert witness in the criminal case, Dr. Lawrence Singer, fentanyl is ''outside the scope of dentistry or oral surgery and 'is only appropriate for a chronic pain patient who has cancer pain or . . . something extremely debilitating and may be chronically ill.' '' 576 F. App'x at 257 (GX 5, at 5). Based on Dr. Singer's testimony, Applicant's admission that he used the fentanyl patch on his back to see if it might relieve oral pain implicates illegal prescribing, dispensing, and use of a Schedule II controlled substance. *See* Tr. 11 (''I will tell the court that you will hear testimony today from . . . [Applicant] regarding . . . his own needs or lack of needs for medication.''). It also evidences Applicant's lack of candor during the DEA investigation and administrative hearing about his history of controlled substance use. *Id.* at 31 (DI testimony) and 111 (Applicant's testimonial denial); GX 6, at 1 (Applicant's written denial); 576 F. App'x at 255 (GX 5, at 4) (recounting testimony of former dental assistant at Eight Felony Conviction Trial).

[11] As already discussed, testimony the United States elicited about the conspiracy count was presented by Applicant's former office manager. She testified that she filled prescriptions Applicant wrote for boxes of fentanyl patches, delivered them to Applicant, and witnessed Applicant apply one patch to his body at the dental office. 576 F. App'x at 255 (GX 5, at 3). The former office manager also testified that Applicant had her print ''multiple prescriptions for controlled substances from the office computer for . . . [his] various family members, patients, and friends.'' *Id.*

Applicant's former dental assistant similarly testified that Applicant wrote a Valium prescription in her name and instructed her to fill it so that he could give it to his girlfriend. 576 F. App'x at 255 (GX 5, at 4). The former dental assistant also testified that Applicant wrote a Vicodin prescription in her name and instructed her to fill it so that he could use it himself. *Id.* She also testified that she learned during the federal investigation of Applicant that he had ''written several other prescriptions in her name which were filled at various pharmacies.'' *Id.*

The Eight Felony Conviction Trial ''Judgment in a Criminal Case'' sheet shows that the second, third, tenth, twelfth, and thirteenth counts are for dispensing controlled substances in violation of 21 U.S.C. 841(a)(1). GX 2, at 1. Applicant also appealed his conviction on these counts arguing that there was ''insufficient evidence to support his distribution offenses.'' 576 F. App'x at 263 (GX 5, at 10). The Fourth Circuit Conviction Affirmance found Applicant's argument to be ''without merit,'' stating ''after a careful review of the record, we conclude substantial evidence clearly supports that . . . [Applicant] distributed and dispensed a variety of controlled substances for recreational purposes and not for a legitimate medical and dental purpose.'' [12] *Id.*

The fourteenth felony count in the indictment of Applicant is health care fraud, a violation of 18 U.S.C. 1347. *Id.* The fifteenth felony count is aggravated identity theft under 18 U.S.C. 1028A. These counts charged Applicant with submitting dental service reimbursement requests under the name of a dentist previously affiliated with the practice to circumvent the health insurance plan's exclusion of services provided to family members. 576 F. App'x at 258 (GX 5, at 5–6). The corroborated testimony received during the Eight Felony Conviction Trial included that Applicant would forge the dentist's signature on the reimbursement checks, sign the checks to himself, and deposit the checks in his personal or business bank account. 576 F. App'x at 258, 264 (GX 5, at 6, 10). The Fourth Circuit Conviction Affirmance concluded that the ''evidence was more than sufficient to show that . . . [Applicant] made the false representations . . . knowingly and willfully, in order to receive money to which he was otherwise not entitled.'' 576 F. App'x at 264 (GX 5, at 10). The restitution ordered upon Applicant's conviction was $91,629.38. GX 2, at 6.

Applicant challenged the health care fraud conviction on two grounds. First, he argued that he was not bound by the terms of the health insurance plan because he was not a party to the contract. 576 F. App'x at 263 (GX 5, at 10). The Fourth Circuit Conviction Affirmance rejected this argument, stating that being a party to an insurance contract ''is not relevant to whether . . . [Applicant] formed the specific intent to commit health care fraud.'' 576 F. App'x at 264 (GX 5, at 10). Second, Applicant claimed that the record evidence was insufficient to support a finding that the health insurance plan was a ''health care benefit program'' as defined by the criminal statute. *Id.* The Fourth Circuit Conviction Affirmance disagreed, concluding that Applicant's health care fraud conviction was supported by ''substantial evidence.'' [13] 576 F. App'x at 264 (GX 5, at 10–11).

In sum, the Fourth Circuit Conviction Affirmance found no reversible error and affirmed the results of the Eight Felony Conviction Trial. 576 F. App'x at 254 (GX 5, at 3).

GX 3 is the VBD Order regarding Applicant's state dental license. Applicant testified about his post-release preparations for, and his participation in, the ''14-hour [VBD] hearing nonstop . . . [that] lasted until 2:00 a.m.'' Tr. 50–51. The Order notes Applicant's appearance at the hearing ''not represented by legal counsel.'' GX 3, at 1. The VBD's post-hearing Order reinstated, indefinitely suspended, and then stayed the indefinite suspension of Applicant's dental license ''contingent upon continued compliance'' with specified terms and conditions. *Id.* at 10–11. As already discussed, those terms and conditions include ''not prescrib[ing] or dispens[ing] Schedule II, III, and IV controlled substances for a period of two (2) years from the date of this Order.'' *Id.* at 11. The terms and conditions also include timely completion of VBD Executive Director-approved, face-to-face, interactive continuing education programs in Principles of Pharmacology and Prescription Writing (seven hours), Treatment of Medically Compromised Patients (four hours), Diagnosis and Treatment Planning Protocol (ten hours), and Ethics for the Dental Professional (seven hours), and undergoing annual random audits of ten patient charts for two years.[14] *Id.*

The ''Findings of Fact'' section of the VBD Order spans eight pages. GX 3, at 1–8. It lists, among other things, eight categories of fact findings about Applicant's illegal actions related to controlled substances from 2006 through 2011.[15] The categories are (1) providing a Schedule III controlled substance to a patient outside of his dental office without a legitimate dental purpose on multiple occasions, (2) prescribing Schedule II through IV controlled substances to eight patients

[12] Testimony the United States elicited about the unlawful distribution and dispensing counts included testimony from a patient whose relationship with Applicant later became romantic. 576 F. App'x at 256 (GX 5, at 4). She testified that ''she would call . . . [Applicant] to get prescriptions for Vicodin and Valium for recreational use, and she would consume these controlled substances as well as alcohol while on dates'' with Applicant. *Id.* She testified that, to obtain these prescriptions, she had to ''hang out'' with Applicant. She stated that on at least one occasion, she combined Vicodin with alcohol and ''blacked out.'' *Id.* Shortly after one such occurrence, she testified, Applicant sent her photographs he had taken of her ''while she was incapacitated, which depicted her nude except for a jacket and a single boot, lying apparently unconscious on his bed.'' *Id.* She testified that she was using the controlled substances, with Applicant's knowledge, ''solely for recreational purposes.'' *Id.* Dr. Singer testified that Applicant performed ''minor dental procedures'' on this patient/girlfriend ''that would result in 'mild discomfort' at most.'' *Id.* The expert also testified that ''between 2007 and 2008 . . . [Applicant] prescribed . . . [for this patient/girlfriend] 'several hundred pills total' in prescriptions that 'were maybe a couple dozen,' '' and that the patient/girlfriend's ''patient record was devoid of any clinical notes to support this treatment.'' *Id.*

The fentanyl patch testimony of Applicant's former office manager was also relevant to these counts. Dr. Singer found that Applicant ''wrote prescriptions . . . [for her] for what [a]ll amounted to a few hundred—several hundred doses of narcotics.' '' 576 F. App'x at 257 (GX 5, at 5). According to the expert, a fentanyl patch is ''outside the scope of dentistry or oral surgery and 'is only appropriate for a chronic pain patient who has cancer pain or . . . something extremely debilitating and may be chronically ill.' '' *Id.*

Likewise, the testimony of Applicant's former dental assistant/patient was relevant to these counts. Dr. Singer opined that Applicant had no clinical notes to support the writing of Valium or Vicodin prescriptions for her. *Id.* The expert concluded that ''these prescriptions were not written within the bounds of dental practice for a legitimate dental purpose.'' *Id.*

[13] The Fourth Circuit Conviction Affirmance also addressed, and found meritless, Applicant's claims of error based on *Brady* v. *Maryland.* 576 F. App'x at 259–62 (GX 5, at 7–9). Its analysis of the error claims addressed, among other things, Applicant's former office manager and her testimony in the Eight Felony Conviction Trial. According to the Fourth Circuit Conviction Affirmance, Applicant's counsel ''conducted a thorough cross examination'' of the former office manager. 576 F. App'x at 260–61 (GX 5, at 7–8). The areas covered by the ''zealous'' cross examination included Applicant's having terminated her for making a false statement to an insurance company, her submitting a false résumé to a local doctor, her submitting a false bill to an insurance company and pocketing the reimbursement check, her forging Applicant's signature on prescriptions, her making inconsistent statements to the grand jury, her submission of fraudulent insurance claims for her sister, her conviction for writing false checks, and her embezzling from Applicant's 401(k) plan. 576 F. App'x at 261 (GX 5, at 8).

[14] The Order also imposed on Applicant administrative costs of $5,000.00. GX 3, at 12.

[15] The VBD Order also documents fact findings about Applicant's provision of care and treatment to a patient that was recorded in a fraudulently created patient record under an alias, fraudulent contracting of health insurance coverage for eleven individuals, and provision of dental treatment to a 92 year old patient without consulting and/or documenting any consultation with the patient's physician concerning the patient's heart defect or heart murmur and atrial fibrillation, without explaining the proposed treatment plan, providing an estimate, or obtaining consent, without appropriately documenting the patient's treatment records, without billing for the correct (lower cost) metal used, and without explaining deceptive or misleading abbreviations in correspondence to the patient. GX 3, at 2, 7–8.

and an individual on multiple occasions without a legitimate dental purpose, (3) prescribing Schedule II and IV controlled substances under the name of an office employee and asking that employee to pick up those prescriptions from the pharmacy for him, (4) instructing the office employee to lie to investigators about these pain medications by stating that Applicant had written them for the employee, (5) excessively prescribing Schedule II, III, and IV controlled substances to two patients beyond a legitimate dental purpose, (6) prescribing to two patients Schedule II controlled substances without a legitimate purpose around the time of office appointments at which x-rays were taken but neither treatment nor the prescriptions were noted in the patient's dental record, (7) prescribing Schedule II controlled substances to six patients without recording the prescriptions in the patient's dental record, and (8) accessing the Virginia Prescription Monitoring Program to obtain information about multiple patients without patient authorization and without a legitimate dental purpose.[16] *Id.* at 2–6. In sum, the VBD Order documents Applicant's unlawful dispensing of 2,711 dosage units of controlled substances in Schedule II (1,740 dosage units), Schedule III (290 dosage units), and Schedule IV (681 dosage units).

E. Applicant's Case

At the hearing, Applicant testified and called one other witness, his current assistant. Tr. 9, 55. He also introduced five exhibits concerning ''the circumstances and . . . the work that . . . [Applicant] has done.'' *Id.* at 12.

During his testimony, Applicant described his credentials and professional affiliations, the establishment and nature of his current dental practice, when he would prescribe Schedule V controlled substances in his current practice, and his ''feel[ing] like . . . [he is currently] helping . . . [patients] 80 percent of the way versus if they had muscle relaxants to take at night . . . which helps them not clench and grind and so forth from being in the wrong bite position. That would help them.'' [17] *Id.* at 44–45, 54–57, 45–46, 46–48, and 48, respectively.

Applicant admitted that he was convicted of eight federal felonies in the Eastern District of Virginia and, regarding fault, stated, ''The buck stops here. It's a hundred percent my fault.'' *Id.* at 48–49. He elaborated on why he was at fault by stating, ''I am responsible to guard my DEA number, to prescribe and document properly anything I prescribe that's controlled and I was perhaps a little bit lax about it.'' *Id.* at 49. Applicant admitted that ''it's easier before to blame others. But, you know, when I had a lot of time to reflect, it was 100 percent me because I'm the boss, I own the practice. Everything should be my responsibility.'' *Id.* at 49–50.

Applicant admitted that the VBD ''suspended . . . [his] license because of the convictions.'' *Id.* at 50. The VBD suspension was ''automatic'' and he ''had never met with them at the time,'' he stated. *Id.* After a ''14-hour [VBD] hearing nonstop . . . [that] lasted until 2:00 a.m.,'' the VBD reinstated his license, although only allowing him to prescribe Schedule V controlled substances. *Id.* at 50–51. In the course of his testimony about the requirements imposed on him by the VBD, Applicant described the one-on-one courses he paid $13,500 to take at Virginia Commonwealth University, recounted a pre-conviction experience he had with a drug-seeking ''soccer Mom,'' and detailed his reaction to patient push-back he received when he prescribed five Vicodin.[18] *Id.* at 57–88, 78–82, 76–77, respectively.

Applicant testified that he had just received a letter from the VBD about the unannounced inspection that was conducted pursuant to Term #3 of the VBD Order and the ensuing VBD review of the inspection report and patient records. *Id.* at 108–09. According to the letter, the VBD found Applicant ''to be in compliance with Term #3 of . . . [the] Order and no violations were noted. Case No. 178272 is CLOSED with no further action necessary.'' RX 6, at 1 [emphasis in original]. Although the VBD informed Applicant that he would be subject to another audit, one that would be announced, Applicant testified that he had paid the $5,000 VBD administrative fee and that there were no other VBD conditions with which he still had to comply. Tr. 110–11.

Applicant testified about other courses, such as in cosmetic dentistry, he has taken, stating that ''I do a lot of continuing education . . . . I'm constantly taking courses all over the country.'' *Id.* at 88; RX 3. He also discussed the post-conviction speeches he presented and articles he wrote. *Id.* at 90–97, 98–103, 124–130; RX 4; RX 5. Applicant testified that he ''just wanted to get that information out there,'' so that it would not ''happen to anyone else.'' Tr. 91. He stated that his ''whole point about it is, you are responsible. . . . [I]t doesn't matter if one of your employees does something, if you are lax about where you keep your prescription pad, it comes back to haunt you, it comes back to bite you, it's a privilege to have the DEA license.'' [19] *Id.* at 92. He also stated that his ''problem'' was that he did not ''properly document prescriptions.'' *Id.* at 94. ''[H]ow to properly document. . . . [Y]ou think it's a pain in the butt, try what I went through, that's a pain in the butt,'' he testified. *Id.*

Applicant specifically addressed what he had ''previously said in an email or on an application,'' presumably concerning his amending the DEA application he submitted from requesting only Schedule V authority to requesting Schedule II through V authority. *Id.* at 50. ''[P]art of it was I had just finished a grueling process . . .—when I was released, of preparing for the . . . [VBD] . . . for reinstatement because they suspended my license because of the convictions,'' he began. *Id.* ''[J]ust rehashing everything in my mind and going through everything with the . . . [VBD],'' he continued. *Id.* Applicant also stated that, ''when I went onto the application . . . and that was just fresh in my mind that it was, you know, there are some things that happen in the office that were still my responsibility.'' [20] *Id.* at 51. Prefacing his final points with the note that he was not represented by counsel at the time, he stated that ''the way I thought about it was I could apply for my DEA,

[16] Applicant admitted to a VBD investigator that, after writing eight prescriptions for a total of 150 dosage units of hydrocodone without recording them in the patient's dental record, he ''subsequently determined'' that the ''patient'' was ''exhibiting drug-seeking behaviors and that he did not write any prescriptions'' for the ''patient'' thereafter. GX 3, at 6.

[17] Applicant testified that his practice has ''around 300'' patients, ''a good 40 percent'' of whom he treated prior to being criminally convicted, and that ''the patients who are returning . . . still come'' even though he does not prescribe controlled substances. Tr. 56–57. He denied that he expects his ''income to change significantly or at all'' if DEA allows him to prescribe Schedule V controlled substances and represented that, prior to being criminally convicted, ''[z]ero . . . percent'' of his income ''was derived from Schedule 2 through 5 prescriptions.'' *Id.* at 113–14. Applicant stated that ''the only thing that would change is the patients would be more comfortable with the muscle relaxants, that's it.'' *Id.* at 113.

[18] ''I've had patients tell me if I give them five Vicodin, they say 'Five? My physician gives me 90.' I say, 'Well, yeah, I'm not your physician,' you know. So, I don't know who needs 90, but those kind of things can end up on the streets.'' Tr. 76.

[19] Applicant's article entitled ''Fraud and Embezzlement in the Dental Office—Part 2,'' for example, offers a variety of suggestions about how to prevent fraud, such as obtaining background checks before hiring employees, reviewing credit card statements, and using software application audit trails. RX 4, at 4.

[20] While not stated explicitly, this portion of Applicant's testimony appears to concern his DEA application.

because they said I could apply for my DEA license . . . [and] 'Okay, but I just won't prescribe Schedule anything but Schedule 5,' you know, I didn't really know at the time,'' he testified. *Id.* at 51–52.

Applicant listed the changes he made in his practice since his felony convictions. He stated that ''[e]verything is in a locked safe . . . , you need a key and a combination . . . [, and] [t]here's a camera on it.'' *Id.* at 97. He testified that ''you can't print prescriptions,'' ''[t]here's no prescriptions lying around anywhere,'' and ''I document like crazy.'' *Id.; see also id.* at 118–19.

Applicant testified that the only time he took a controlled substance was ''15 years ago or something . . . [when] the oral surgeon prescribed . . . [him] Tylenol #3 or something back then.'' *Id.* at 111. He stated that he has never been treated for addiction to any narcotics or any drugs, and that he has ''zero'' drug problem. *Id.* On cross examination, he testified that, before the criminal convictions, he only directed staff to pick up blood pressure and cholesterol prescriptions for him from the pharmacy; ''never, ever . . . any medication that was not prescribed to'' him. *Id.* at 115.

The Chief ALJ, who observed Applicant's demeanor during the hearing, assessed Applicant's credibility and included his observations and conclusions in the RD. According to the Chief ALJ, ''Even beyond the obvious reality that, as the applicant, the . . . [Applicant] has the most at stake regarding the outcome of the proceedings, his presentation conflicted with the incontrovertible evidence, was blatantly self-serving, and struck as inconsistent even with his own exhibits.'' RD, at 25. The Chief ALJ concluded that ''there was some testimony of the . . . [Applicant] that can certainly be credited in this recommended decision, such as biographical information . . . . Where his recitation of relevant facts conflicts with incontrovertible evidence, such as facts subsumed by his convictions and the findings rendered by the . . . [VBD], his testimony is not just legally incapable of belief; it is factually unworthy of credibility.'' *Id.*

My review and analysis of the record are consistent with the Chief ALJ's conclusions. For example, according to the record transcript, Applicant testified that the only time he took a controlled substance was ''15 years ago or something . . . [when] the oral surgeon prescribed . . . [him] Tylenol #3 or something back then.'' Tr. 111. According to the Fourth Circuit Conviction Affirmance, however, Applicant ''corroborated'' his former office manager's testimony that he applied a fentanyl patch to his body in her presence.[21] 576 F. App'x at 256 (GX 5, at 4).

By way of further example, the Chief ALJ asked Applicant whether it would be incorrect ''if someone said that . . . [he] intentionally wrote up prescriptions or gave them to people for other than a legitimate medical purpose.'' Tr. 121. Applicant agreed, ''That would be wrong.'' *Id.* As already discussed, however, both the Fourth Circuit Conviction Affirmance and the VBD Order conclusively found that Applicant intentionally wrote controlled substance prescriptions for other than a legitimate medical purpose. 576 F. App'x at 256–57 (GX 5, at 4–5); GX 3, at 2–5.

Applicant's lack of credibility is exhibited in ways in addition to blatant conflicts between his record testimony and the records of the Eight Felony Conviction Trial, the Fourth Circuit Conviction Affirmance, and the VBD Order. For example, Applicant could have sought access to, and potentially introduced into the record, Prescription Drug Monitoring files to support his answer to his own counsel's question about whether he ever took Schedule II or Schedule III controlled substances. Tr. 111. There are no such files in the record, however. Neither did Applicant submit any evidence explaining why he did not seek to obtain or offer any such corroborating evidence.

By way of further example, Applicant testified that the software used in his dental office, Dentrix, includes an audit trail, ''[s]o, everything that's put in there cannot be erased.'' *Id.* at 100. Applicant detailed that ''if somebody prints a prescription out and deletes it out of the system, . . . [Dentrix] documents that somebody, under their login, printed a prescription and deleted it. *Id.* at 100–01. Applicant even testified that he showed evidence from Dentrix to the VBD and the VBD stated ''why is this even an issue,'' whereas he ''told the FBI about those digital records and they just never did anything about it.'' *Id.* at 122. Yet, although Applicant suggested that Dentrix audit trails would exonerate him, the record in this matter does not contain a single Dentrix audit trail. The record also does not contain Applicant's explanation as to his failure to offer the exonerating evidence he claimed exists.

In sum, I agree with the Chief ALJ's credibility assessment of Applicant. Further, I afford no weight to Applicant's claims of innocence when he failed to produce the documentary evidence that he testified exists and supports those innocence claims.[22]

The second witness Applicant called was his current assistant, a certified dental assistant (hereinafter, CDA), whose employment with him began after his release from incarceration. *Id.* at 138. CDA testified about her job responsibilities and stated that Applicant gave her ''general information'' about ''what happened and that his license was suspended and he couldn't practice for some time.'' *Id.* at 137–38. She testified that Applicant keeps his prescription pads in a safe, that there is a camera trained on the safe, and that a key and a combination are needed to open the safe. *Id.* at 139. CDA stated that the dental office uses the ''Dentrix system,'' but that only Applicant knows the passwords to it. *Id.* at 140. She denied seeing Applicant prescribe a controlled substance or take a controlled substance, and seeing Applicant use anyone else's prescription pad or DEA number. *Id.* at 141–42. CDA testified that Applicant never asked her to ''phone in any sort of Schedule[d] substances.'' *Id.* at 142. She stated that she has heard patients ask Applicant to prescribe ''something stronger than ibuprofen or Motrin or Tylenol'' and that Applicant replied to ''just take Advil and Tylenol.'' *Id.* at 142–43.

I agree with the Chief ALJ's assessment that CDA's ''testimony presented no basis to conclude that she was not credible. She appeared candid and forthright, and her testimony was sufficiently detailed, internally consistent, and plausible to be fully credited.'' RD, at 27.

F. Allegation That Applicant Was Convicted of Felonies Related to Controlled Substances

As already discussed, the OSC charged that Applicant's application for a registration should be denied due to his having been convicted of six felonies related to controlled substances. OSC, at 1. Applicant does not dispute that he was criminally convicted of eight felonies in the Eastern District of

[21] Fentanyl is a Schedule II controlled substance.

[22] This Agency has applied, and I apply here, the ''adverse inference rule.'' As the D.C. Circuit explained, ''Simply stated, the rule provides that when a party has relevant evidence within his control which he fails to produce, that failure gives rise to an inference that the evidence is unfavorable to him.'' *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. (UAW)* v. *Nat'l Labor Relations Bd.,* 459 F.2d 1329, 1336 (D.C. Cir. 1972). The Court reiterated this rule in *Huthnance* v. *District of Columbia,* 722 F.3d 371, 378 (D.C. Cir. 2013). According to this legal principle, Applicant's decision not to provide evidence within his control gives rise to an inference that any such evidence is unfavorable to Applicant.

Virginia. Tr. 48–49. Based on the uncontroverted evidence in the record, I find that six of these undisputed felony convictions, Applicant's convictions for conspiracy to dispense controlled substances illegally under 21 U.S.C. 846 and for illegally distributing or dispensing controlled substances under 21 U.S.C. 841(a)(1), relate to controlled substances.[23] GX 2; GX 5; *see also* GX 3, at 1–2.

III. Discussion

A. The Controlled Substances Act and the Public Interest Factors

Pursuant to section 303(f) of the CSA, ''[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . 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). Section 303(f) further provides that an application for a practitioner's registration may be denied upon a determination that ''the issuance of such registration . . . would be inconsistent with the public interest.'' *Id.* In making the public interest determination, the CSA requires consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing . . . controlled substances.

(3) The applicant'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.

Id.

These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether . . . an application for registration [should be] denied.'' *Id.* Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one,'' and I ''can 'give each factor the weight . . . [I] determine[ ] is appropriate.' '' *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009) quoting *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005)). In other words, the public interest determination ''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; what matters is the seriousness of the registrant's misconduct.'' *Peter A. Ahles, M.D.,* 71 FR 50097, 50098–99 (2006).

Pursuant to section 304(a)(2), the Attorney General is authorized to suspend or revoke a registration ''upon a finding that the registrant . . . has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States . . . relating to any substance defined in this subchapter as a controlled substance or a list I chemical.'' 21 U.S.C. 824(a)(2). It is well established that the various grounds for revocation or suspension of an existing registration that Congress enumerated in this section are also properly considered in deciding whether to grant or deny an application under section 303. *See Richard J. Settles, D.O.,* 81 FR 64940, 64945 (2016); *Arthur H. Bell, D.O.,* 80 FR 50035, 50037 (2015); *Mark P. Koch, D.O.,* 79 FR 18714, 18734–35 (2014); *The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy,* 72 FR 74334, 74338 (2007); *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23852 (2007); *Alan R. Schankman, M.D.,* 63 FR 45260, 45260 (1998); *Kuen H. Chen, M.D.,* 58 FR 65401, 65402 (1993).

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. Both parties submitted documentary evidence. All of the documentary evidence was admitted without objection. *See, e.g.,* ALJX 10, at 1–2 (stipulating to the authenticity of certain evidence). The admitted documentary evidence implicates Factors One, Two, Three, and Four. Of these relevant factors, the OSC first alleges Applicant's controlled substance felony convictions. OSC, at 2–3. Accordingly, Factor Three is discussed first, followed by Factor One, and then Factors Two and Four.

B. Factor Three—Applicant's Felony Convictions Relating to Controlled Substances

As already discussed, I found that Applicant's convictions for conspiracy to dispense controlled substances and for illegally distributing or dispensing controlled substances are six felony convictions relating to controlled substances. *Supra* section II.F. I further find that Applicant's convictions for conspiracy to dispense controlled substances and for illegally distributing or dispensing controlled substances are six felony convictions ''relating to'' controlled substances as those terms are defined in 21 U.S.C. 824(a)(2). 21 U.S.C. 846 and 841(a)(1); *William J. O'Brien, III, D.O.,* 82 FR 46527, 46529 (2017). In addition, with respect to the record evidence, I find that these six felony convictions constitute Applicant's ''conviction record under Federal . . . laws relating to the manufacture, distribution, or dispensing of controlled substances.''[24] 21 U.S.C. 823(f)(3). Accordingly, the CSA, under Factor Three, requires me to consider these six felony convictions in my determination of whether the issuance of a registration to Applicant would be ''inconsistent with the public interest.'' *Id.*

C. Factor One—Recommendation of the Appropriate State Licensing Board

Factor One calls for consideration of the ''recommendation of the appropriate state licensing board or professional disciplinary authority'' in the public interest determination. 21 U.S.C. 823(f)(1). Neither the VBD Order nor any other record evidence constitutes a direct recommendation to the Agency from the VBD about Applicant's registration application.

As already discussed, after suspending Applicant's dental license about ten days after entry of Judgment in the Eight Felony Conviction Trial, the VBD reinstated Applicant's dental license, placed it on indefinite suspension, and stayed that suspension ''contingent upon continued compliance'' with various terms and conditions. GX 3, at 10–11. One such term and condition was that Applicant was not to ''prescribe or dispense Schedule II, III, and IV controlled substances for a period of two (2) years from the date of this Order,'' September 22, 2016. GX 3, at 11–12. Both parties implicitly interpret this VBD term as authorizing Applicant to prescribe and dispense Schedule V controlled substances in Virginia. *See, e.g.,* OSC, at 2.

The record does not include a comparison of the evidence presented in the Eight Felony Conviction Trial and in the VBD hearing. Clearly, though, the Fourth Circuit Conviction Affirmance and the VBD Order do not discuss all of the same incidents or evidence.

[23] I agree with the Chief ALJ's conclusions that, in this case, the felony convictions for health care fraud and aggravated identity theft are not sufficiently related to controlled substances. RD, at 35.

[24] Just as a felony conviction relating to controlled substances provides a basis for revoking an existing registration without proof of any other misconduct, *see* 21 U.S.C. 824(a)(2), it also provides an independent and adequate ground for denying an application. *Mark P. Koch, D.O.,* 79 FR at 18734–35; *Alvin Darby, M.D.,* 75 FR 26993 n.30 (2010); *Brady Kortland Fleming, D.O.,* 46 FR 45841, 45842 (1981).

My predecessor recently addressed Factor One and its application in a matter when the state board granted a doctor limited controlled substance authority based on less evidence of misconduct than the Government had presented during the OSC proceeding. *John O. Dimowo, M.D.,* 85 FR 15800, 15810 (2020).[25] In that case, my predecessor concluded that the state board's input was not a ''direct recommendation'' for purposes of Factor One. *Id.* at 15810. Viewing the state's action as ''indicating a recommendation,'' though, and stating that the CSA clearly places on him the responsibility to conduct the public interest inquiry and analysis, he noted that the state board had ''severely limited'' the doctor's medical license, ''which does not indicate a substantial amount of trust'' in the doctor. *Id.* Pointing out that he had more evidence of misconduct before him than the state board had, he stated that he considered the state board's action in the doctor's favor even though it was based on a subset of the evidence before him. *Id.*

I apply the same analysis and reach the same conclusion here given the differences between the evidence set out in the VBD Order and the evidence before me, including the evidence addressed in the Fourth Circuit Conviction Affirmance. In sum, while the terms of the VBD Order are not dispositive of the public interest inquiry in this case and are minimized due to the differences in the evidence in the VBD Order and the uncontroverted record evidence in this matter, I consider the VBD's grant of Schedule V authority in Applicant's favor.

D. Factors Two and Four—Applicant's Experience Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

Factors Two and Four call for consideration of Applicant's ''experience in dispensing . . . controlled substances'' and his ''[c]ompliance with applicable State, Federal, or local laws relating to controlled substances.'' 21 U.S.C. 823(f)(2) and (4), respectively. I reviewed all of the record evidence concerning Applicant's controlled substance dispensing experience and compliance with applicable laws relating to controlled substances, including the testimony received during the adjudication of this OSC, and Applicant's position on it. I evaluated the evidence using the credibility assessments already discussed. *Supra* section II.E.

Relevant, uncontroverted record evidence concerning Factors Two and Four is in the VBD Order documenting Applicant's unlawful 2,711 dosage unit dispensing of controlled substances in Schedule II (1,740 dosage units), Schedule III (290 dosage units), and Schedule IV (681 dosage units). GX 2, at 2–10; *see also supra* section II.D. The VBD Order also documents the multiple provisions of Virginia law about controlled substances that Applicant violated.[26] GX 3, at 2–10. Other relevant, uncontroverted record evidence concerning Factors Two and Four is in the Judgment of the Eight Felony Conviction Trial and in the Fourth Circuit Conviction Affirmance already discussed.[27] *Supra* section II.D. GX 2, at 1; 576 F. App'x at 254–64 (GX 5, at 3–11).

Other record evidence concerning Applicant's controlled substance experience and dispensing is Applicant's testimony and written communications. During the hearing, for example, Applicant admitted that he wrote prescriptions that he ''shouldn't have written and that was a mistake and that would never, ever happen again.'' Tr. 130. By way of further example, Applicant also admitted that he ''wrote prescriptions, a few prescriptions that were not medically necessary. . . . I made a mistake, stupidity, naiveté, not being responsible.'' *Id.* at 131. He also admitted that he ''authorized a prescription or called a prescription or wrote a prescription that . . . [he did not] really know if it was a legitimate dental purpose, because they didn't come in.'' *Id.* at 129; *see also id.* at 128. Going back to 2006 and 2007, and ''quite a long time ago,'' Applicant testified, he ''made mistakes as far as what I prescribed to certain people.'' *Id.* at 129.

While admitting he wrote controlled substance prescriptions that were not legitimate, Applicant also testified that ''as far as . . . [his] trying to get any kind of favors or money or anything like that, that is not the case.'' *Id.* at 130. Material in the Fourth Circuit Conviction Affirmance conflicts with this testimony. 576 F. App'x, at 256 (GX 5, at 4) (describing a total of several hundred pills that were ''devoid of any clinical notes to support this treatment'' that Applicant prescribed between 2007 and 2008 to a woman with whom he was romantically involved). By way of further example, in written communications with DI, Applicant stated that ''I have never abused, sold drugs or anything like that.'' GX 6, at 1. This is not true according to the Fourth Circuit Conviction Affirmance. 576 F. App'x, at 256–57 (GX 5, at 4–5) (finding it a ''reasonable determination'' for the jury to have credited other witnesses' testimony over Applicant's when Applicant corroborated the testimony of his former office manager that Applicant wrote a prescription for several boxes of fentanyl patches in her name and applied a patch to his body in her presence because he was ''hoping this was something . . . [he] could use as a treatment modality . . . for any oral pain . . . [and wanted] to see if it helps . . . [his] back,'' even though, according to Dr. Singer, a fentanyl patch is ''outside the scope of dentistry or oral surgery and 'is only appropriate for a chronic pain patient who has cancer pain or . . . something extremely debilitating and may be chronically ill'''').

In sum, I carefully considered all of the record evidence relevant to Factors One, Two, Three, and Four and Applicant's arguments about that evidence. I applied my and the Chief ALJ's credibility assessments to that evidence. I conclude that the Government met its *prima facie* burden of showing that it would be ''inconsistent with the public interest'' for me to grant Applicant's registration application for Schedule V authority. 21 U.S.C. 823(f). I further find that Applicant did not rebut the Government's *prima facie* case.

IV. Sanction

Where, as here, the Government presented a *prima facie* case that it would be ''inconsistent with the public interest'' to grant Applicant's request for a Schedule V registration, and Applicant did not rebut the Government's *prima facie* case, Applicant must then ''present[ ] sufficient mitigating evidence'' to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018). Further, as past performance is the best predictor of future performance, Agency

[25] The *John O. Dimowo, M.D.* Agency decision stands for the proposition that ''[a]lthough statutory analysis [of the CSA] may not definitively settle . . . [the breadth of the cognizable state 'recommendation' referenced in Factor One], the most impartial and reasonable course of action is to continue to take into consideration all actions indicating a recommendation from an appropriate state.'' 85 FR at 15810.

[26] Va. Code Ann. sec. 54.1–3303 (West, current through End of the 2016 Reg. Sess.) (amended 2017, 2018, 2019); Va. Code Ann. sec. 54.1–3408 (West, current through End of the 2016 Reg. Sess.) (amended 2017, 2018, 2019). The seriousness and extent of these violations are sufficient bases for my decision in this matter and, therefore, I need not address the other VBD founded violations of Virginia law alleged in the OSC.

[27] 21 U.S.C. 841(a)(1) and 846.

decisions require Applicant's unequivocal acceptance of responsibility for his actions and a demonstration that he will not engage in future misconduct. *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995); *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 463 (2009) (collecting cases); *Jeffrey Stein, M.D.,* 84 FR 46968, 46972–73 (2019). The Agency has decided that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.,* 83 FR at 18910 (collecting cases). The Agency has also considered the need to deter similar acts by Applicant and by the community of registrants. *Id.*

The extent of Applicant's misconduct proven by the record evidence is eight felonies, six of which relate to controlled substances and all of which were affirmed on appeal, and the unlawful dispensing of over 2,700 dosage units of controlled substances in Schedules II, III, and IV. In addition, as already discussed, Applicant's testimony was not always marked by candor. *Supra* sections II.E. and III.D; *see also* GX 3, at 3 (''Individual I stated that in or about 2011, . . . [Applicant] instructed her to tell investigators that he had written prescriptions for pain medications for her, although this was not true.'').

While Applicant took responsibility for some of his wrongdoing, he did not take unequivocal responsibility for all of it. First, despite the Fourth Circuit Conviction Affirmance, Applicant testified that he did not conspire to distribute and dispense controlled substances in violation of 21 U.S.C. 846. Tr. 115 (denying that he ever unlawfully directed employees to go to pharmacies to pick up prescriptions and return them to him); *see also id.* at 133–34. Instead, he blamed his conspiracy conviction on false testimony of his former office manager. *Id.* at 116–17. Second, concerning his convictions for unlawfully dispensing controlled substances, Applicant denied writing prescriptions that did not have a legitimate dental purpose. *Id.* at 116. Instead, he testified that the prescriptions were legitimate. He explained that his ''problem'' was that the prescriptions lacked proof of their legitimacy in the form of proper documentation. *Id.* at 117. Third, he testified that it ''would be wrong'' for someone to say that he intentionally wrote or gave people prescriptions ''for other than a legitimate medical purpose.'' *Id.* at 121. Instead, he attributed what courts and the VBD determined were unlawful prescriptions to his not being careful enough, his making a mistake, his stupidity, and his being lax. *Id.* at 127–31.

As the Chief ALJ stated, ''It would be illogical for the Agency to entrust . . . [Applicant] with the weighty responsibilities of a DEA registrant where he is unable to even accept the proposition that he has engaged in the misconduct that he was convicted of and which was sustained by the . . . [VBD].'' RD, at 42. ''[S]o long as . . . Applicant adheres to his (almost bizarre) state of denial regarding the actual facts subsumed in his convictions (and Board findings),'' the Chief ALJ continued, ''it would be unreasonable to believe that he will alter his conduct.'' *Id.* Thus, as past Agency decisions make clear that unequivocal acceptance of responsibility is a prerequisite for the forbearance of a sanction, Applicant's failure unequivocally to accept responsibility means that he is not eligible to avoid an unfavorable disposition of his application under the record facts in this case.[28]

Applicant testified that he is not currently prescribing controlled substances in his dental practice and that he does not expect the income he realizes from his practice to increase if he had that authority. Tr. 46–48,113–14. Instead, he stated, he would like authority to prescribe Schedule V controlled substances for the sake of his patients' comfort. *Id.* at 46–48; *cf. supra* n.17 (summarizing Applicant's testimony that his not having authorization to dispense controlled substances has not dissuaded patients from using his practice). Applicant does not cite, and I am unaware of, any past Agency decision that grants a registration for the sake of patient comfort when the applicant was convicted of eight felonies and the unlawful dispensing of over 2,700 controlled substance dosage units. I decline to suggest, let alone establish, such a path.

I agree with the Chief ALJ that ''consideration of the egregiousness of . . . [Applicant's] transgressions likewise does not support a sanction less than an outright denial of . . . [Applicant's] application.'' RD, at 43.

The record in this case paints a picture of a registrant out of control. He distributed and dispensed drugs to himself and others with no justifiable reason, tasked his employees with taking controlled substance scrips to pharmacies and filling them so that he could dole them out to himself, friends, and other non-patients, slapped a fentanyl patch on himself in front of his staff, handed out powerful controlled drugs to his love interests, and prescribed scores of controlled substances to multiple patients without a legitimate medical purpose.

Id. In this context, specific and general deterrence weigh in favor of denying the application. I agree with the Chief ALJ that ''[t]o issue a registration to this . . . [Applicant] would send a message to the regulated community that misconduct (even repeated serious, intentional misconduct) will bear no meaningful consequence, even after state board findings and convictions,'' if the Applicant ''deflects blame onto others.'' *Id.*

Given my decision that Applicant's application is not in the public interest, I conclude that Applicant's proposed Corrective Action Plan provides no basis for me to discontinue or defer this proceeding.

Accordingly, I shall order the denial of Applicant's application.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny the application submitted by Hamada Makarita, D.D.S., Control No. W16093263C, seeking registration in Virginia as a practitioner in Schedule V, and any other pending application submitted by Hamada Makarita, D.D.S. for a DEA registration in the Commonwealth of Virginia. This Order is effective August 28, 2020

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–16355 Filed 7–28–20; 8:45 am]

BILLING CODE 4410–09–P

[28] Applicant testified about the changes he made to his dental practice after his felony convictions and the VBD Order. Those so-called ''remedial measures,'' however, ''bear no logical nexus to his established misconduct'' of misusing his controlled substance privileges, as the Chief ALJ observed. RD, at 41. While Applicant testified about the expensive educational courses he took and the ''measures calculated to protect his scripts and prescribing software from potential malfeasance of staff members and burglars,'' he introduced no remedial measure ''that might bear the capacity to protect these powerful tools from his own future malfeasance.'' *Id.*

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–684]

Bulk Manufacturer of Controlled Substances Application: Euticals Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before September 28, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on June 5, 2020, Euticals Inc., 2460 W Bennett Street, Springfield, Missouri 65807–1229, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid.	2010	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Phenylacetone	8501	II
Methadone	9250	II
Methadone intermediate	9254	II
Oripavine	9330	II
Tapentadol	9780	II

The company plans to manufacture the above-listed controlled substances in bulk for distribution to its customers. No other activities for these drug codes are authorized for this registration.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020–16401 Filed 7–28–20; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–687]

Bulk Manufacturer of Controlled Substances Application: Siegfried USA, LLC

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before September 28, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on May 21, 2020, Siegfried USA, LLC, 33 Industrial Park Road, Pennsville, New Jersey 08070–3244, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Amphetamine	1100	II
Tapentadol	9780	II

The company plans to manufacture the above-listed controlled substances in bulk for sale to its customers.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020–16397 Filed 7–28–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1190–NEW]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Generic Clearance for Pilot and Field Studies for Community Relations Service Data Collection Activities

AGENCY: Community Relations Service, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Community Relations Service (CRS), intends to request approval from the Office of Management and Budget (OMB) for a generic information collection clearance that will allow CRS to conduct a variety of participant feedback studies. CRS will submit the request for review and approval in accordance with the Paperwork Reduction Act of 1995. Over the next three years, CRS anticipates collecting program impact evaluation data for reassessing ongoing programs across several areas within community outreach. The purpose of these collections is to gather feedback from participants who attended CRS programs and to use that information to measure the impact of the programs. This work may entail redesigning and/or modifying existing programs based upon received feedback. CRS envisions using surveys, interviews, and other electronic data collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until September 28, 2020.

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 Community Relations Service, 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.

—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, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New Generic Information Collection Request.

(2) *The Title of the Form/Collection:* Generic Clearance for Community Relations Service Program Impact Evaluations.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form numbers not available for generic clearance. The applicable component within the Department of Justice is the Community Relations Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Participants of CRS programs in relevant jurisdictional fields; individuals; facilitators; state and local law enforcement, government officials, faith leaders, and community leaders; students; school administrators; and representatives of advocacy organizations.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* We estimate that approximately 80–90 respondents will be involved in program impact evaluations conducted under this clearance over the requested 3-year

clearance period. The average response time per respondent will be up to 1 hour.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total respondent burden for identified and future projects covered under this generic clearance over the 3-year clearance period is approximately 80–90 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, 3E.405A, Washington, DC 20530.

Dated: July 23, 2020.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020–16352 Filed 7–28–20; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Office of the Secretary

All Items Consumer Price Index for All Urban Consumers; United States City Average

Pursuant to Section 112 of the 1976 amendments to the Federal Election Campaign Act, 52 U.S.C. 30116(c), the Secretary of Labor has certified to the Chairman of the Federal Election Commission and publishes this notice in the **Federal Register** that the United States City Average All Items Consumer Price Index for All Urban Consumers (CPI–U) (1967 = 100) increased 418.5 percent from its 1974 annual average of 147.7 to its 2019 annual average of 765.836 and that it increased 44.4 percent from its 2001 annual average of 530.4 to its 2019 annual average of 765.836. Using 1974 as a base (1974 = 100), I certify that the CPI–U thus increased 418.5 percent from its 1974 annual average of 100 to its 2019 annual average of 518.508. Using 2001 as a base (2001 = 100), I certify that the CPI–U increased 44.4 percent from its 2001 annual average of 100 to its 2019 annual average of 144.388. Using 2006 as a base (2006 = 100), I certify that the CPI–U increased 26.8 percent from its 2006 annual average of 100 to its 2019 annual average of 126.815.

Signed at Washington, DC.

Eugene Scalia,

Secretary of Labor.

[FR Doc. 2020–16380 Filed 7–28–20; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Office of the Secretary

All Items Consumer Price Index for All Urban Consumers; United States City Average

Pursuant to Section 33105(c) of Title 49, United States Code, and the delegation of the Secretary of Transportation's responsibilities under that Act to the Administrator of the Federal Highway Administration (49 CFR, Section 1.95(a)), the Secretary of Labor has certified to the Administrator and published this notice in the **Federal Register** that the United States City Average All Items Consumer Price Index for All Urban Consumers (1967=100) increased 146.2 percent from its 1984 annual average of 311.1 to its 2019 annual average of 765.836.

Signed at Washington, DC.

Eugene Scalia,

Secretary of Labor.

[FR Doc. 2020–16379 Filed 7–28–20; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Veterans' Employment and Training Service

Agency Information Collection Activities; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL) Veterans' Employment and Training Service (VETS) is soliciting comments concerning a proposed authority to conduct the information collection request (ICR) titled, ''Employment Navigator Data Collection and Matching.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by September 28, 2020.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained at no cost by contacting Luke Murren by telephone at 202–693–4711 (this is not a toll-free number), or by email at *Murren.Luke@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Veterans' Employment and Training Service, Transition Assistance Program, 200 Constitution Ave. NW, Room S1212, Washington, DC 20210; or by email: *Murren.luke@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Luke Murren by telephone at 202–693–4711 (this is not a toll-free number) or by email at *Murren.Luke@dol.gov.*

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

DOL seeks approval of a new information collection request (ICR) titled ''Employment Navigator Data Collection and Matching''. This request is for a ''common forms'' clearance process. There are three forms included in this ICR. The first form is a data collection mechanism for transitioning service members to provide general characteristics and background information as services are received from Employment Navigators. The second form includes additional data that is captured from government and non-government partners who will provide the service member, veteran, or spouse addition job seeker assistance after Employment Navigator data entry is complete. This form also includes any employment-related outcomes (*e.g.,* job placement, job retention, and hourly wages earned) for each participant. The last form is a registration and validation form that all necessary partner entities must complete in order to be considered for partner status.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown

in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB 1205–0NEW.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- 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).

Agency: DOL–VETS.

Type of Review: NEW.

Title of Collection: Employment Navigator Data Collection and Matching.

Forms: Employment Navigator Intake (VETS–NEW1); Employment Navigator Partner Intake (VETS–NEW2); Employment Navigator Partner Validation Input (VETS–NEW3).

OMB Control Number: 1205–0NEW.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 22,550.

Frequency: Annually.

Total Estimated Annual Responses: 22,550.

Estimated Average Time per Response: Varies.

Estimated Total Annual Burden Hours: 6,885 hours.

Total Estimated Annual Other Cost Burden: $204,425.25.

John Lowry,

Assistant Secretary for Veterans' Employment and Training Service.

[FR Doc. 2020–16378 Filed 7–28–20; 8:45 am]

BILLING CODE 4510–79–P

LEGAL SERVICES CORPORATION

Assessing the Goals in the Strategic Plan 2017–2020; Request for Comments

AGENCY: Legal Services Corporation.

ACTION: Request for comments.

SUMMARY: The Legal Services Corporation (''LSC'') Board of Directors (''Board'') is in the process of updating LSC's strategic plan for the years 2021–2024. The LSC Board is soliciting comments on the current LSC Strategic Plan 2017–2020 and whether the current goals and initiatives remain suitable and timely and if new goals or initiatives should be implemented.

DATES: All comments and recommendations must be received on or before the close of business on August 28, 2020.

ADDRESSES: You may submit comments by email to *LSCStrategicPlan@lsc.gov;* cc: Helen Guyton, Assistant General Counsel, *guytonh@lsc.gov*.

Instructions: All comments should be addressed to Rebecca Fertig Cohen, Chief of Staff, Legal Services Corporation. Include ''Assessing Strategic Plan Goals 2017–2020'' as the heading or subject line for all comments submitted.

FOR FURTHER INFORMATION CONTACT: Rebecca Fertig Cohen, *cohenr@lsc.gov,* (202) 295–1576.

SUPPLEMENTARY INFORMATION: Created and funded by Congress, LSC's fundamental mission is to pursue equal access to our justice system and serve as the single largest funder of civil legal aid programs in the country. With this mission in mind, the LSC Board adopted a plan in 2012 setting forth the strategic goals that would guide LSC for five years, ending in 2016 (''Initial Strategic Plan''). The LSC Board updated the Initial Strategic Plan for an additional four-year period covering 2017–2020 (''LSC Strategic Plan 2017–2020''). The LSC Board is now in the process of updating and revising the strategic plan for an additional four-year period from 2021–2024. As part of this process, the LSC Board is seeking input from the public and interested stakeholders on whether the goals articulated in the current LSC Strategic Plan 2017–2020, which is available at *https://www.lsc.gov/about-lsc/who-we-are/strategic-plan,* are still suitable and timely and whether new goals, if any, should be considered. A summary of the goals follows.

The first and primary goal listed in the LSC Strategic Plan 2017–2020 is to maximize the availability, quality, and effectiveness of the civil legal services that LSC's grantees provide to eligible low-income individuals. LSC identifies three avenues through which it can best accomplish this goal: (1) Continue the identification, validation, and sharing of best practices to ensure grantees are most effectively meeting the civil legal needs of low-income Americans; (2) continue the development and implementation of meaningful performance standards and metrics to ensure assessment of grantees in as fair, objective, and effective a way as possible while supporting the best possible performance of all grantees; and (3) provide legal practice and operational support to grantees to further improve the quality of civil legal services to low-income Americans and assess and prioritize actions to ensure grantees have the training and technical assistance required to support grantees effectively.

The second goal listed in the LSC Strategic Plan 2017–2020 is to expand the role of LSC as a convener and leading voice for civil legal services for eligible persons living in poverty in the United States.

The third and final goal listed in the LSC Strategic Plan 2017–2020 is to continue to achieve the highest standards of fiscal responsibility both for itself and its grantees. As a steward of congressional funds collected from the American taxpayer, LSC has a duty to prudently use the resources allocated to it. LSC's goal is to comply with the parameters expressed by Congress and conform to the highest professional standards of fiscal transparency and accountability, both within the Corporation and in its fiscal oversight of those who receive funds from LSC.

Dated: July 23, 2020.

Stefanie Davis,

Senior Assistant General Counsel.

[FR Doc. 2020–16360 Filed 7–28–20; 8:45 am]

BILLING CODE 7050–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–79; NRC–2020–0172]

In the Matter of Wolf Creek Nuclear Operating Corporation; Wolf Creek Generating Station; Independent Spent Fuel Storage Installation

AGENCY: Nuclear Regulatory Commission.

ACTION: Order; modification.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued a general license to the Wolf Creek Nuclear

Operating Corporation (Wolf Creek), authorizing the operation of the Wolf Creek Generating Station Independent Spent Fuel Storage Installation (ISFSI), in accordance with its regulations. The Order is being issued to Wolf Creek to impose additional security requirements because Wolf Creek has identified near term plans to store spent fuel in an ISFSI under the general license provisions of the NRC's regulations. The Order was issued July 22, 2020 and became effective immediately.

DATES: This Order became effective on July 22, 2020.

ADDRESSES: Please refer to Docket ID NRC–2020–0172 or NRC Docket No. 72–0079 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0172. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Tomeka Terry, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Rockville, MD 20852; telephone: 301–415–1488; email: *Tomeka.Terry@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the Order is attached.

Dated: July 23, 2020.

For the Nuclear Regulatory Commission.

John W. Lubinski,

Director, Office of Nuclear Material Safety and Safeguards.

Attachment—Order

In the Matter of Wolf Creek Nuclear Operating Corporation; Wolf Creek Generating Station; Independent Spent Fuel Storage Installation; Order Modifying License (Effective Immediately)

I

Pursuant to § 2.106 of title 10 of the *Code of Federal Regulations* (10 CFR), the NRC (or the Commission) is providing notice, in the matter of Wolf Creek Nuclear Operating Corporation's Independent Spent Fuel Storage Installation (ISFSI) Order Modifying License (Effective Immediately). The text of the Order (not including Attachment 1, which contain Safeguards Information) is as follows.

II

The NRC has issued a general license to Wolf Creek Nuclear Operating Corporation, (Wolf Creek), authorizing the operation of an ISFSI, in accordance with the Atomic Energy Act of 1954, as amended, and 10 CFR part 72. This Order is being issued to Wolf Creek because WOLF CREEK has identified near-term plans to store spent fuel in an ISFSI under the general license provisions of 10 CFR part 72. The Commission's regulations at 10 CFR 72.212(b)(5), 10 CFR 50.54(p)(1), and 10 CFR 73.55(c)(5) require licensees to maintain safeguards contingency plan procedures to respond to threats of radiological sabotage and to protect the spent fuel against the threat of radiological sabotage, in accordance with 10 CFR part 73, appendix C. Specific physical security requirements are contained in 10 CFR 73.51 or 73.55, as applicable.

Inasmuch as an insider has an opportunity equal to, or greater than, any other person, to commit radiological sabotage, the Commission has determined these measures to be prudent. Comparable Orders have been issued to all licensees that currently store spent fuel or have identified near-term plans to store spent fuel in an ISFSI.

III

On September 11, 2001, terrorists simultaneously attacked targets in New York, NY, and near Washington, DC, using large commercial aircraft as weapons. In response to the attacks and intelligence information subsequently obtained, the Commission issued a number of Safeguards and Threat Advisories to its licensees to strengthen licensees' capabilities and readiness to respond to a potential attack on a nuclear facility. On October 16, 2002, the Commission issued Orders to the licensees of operating ISFSIs, to place the actions taken in response to the Advisories into the established regulatory framework and to implement additional security enhancements that emerged from NRC's ongoing comprehensive review. The Commission has also communicated with other Federal, State, and local government agencies and industry representatives to discuss and evaluate the current threat environment in order to assess the adequacy of security measures at licensed facilities. In addition, the Commission has conducted a comprehensive review of its safeguards and security programs and requirements.

As a result of its consideration of current safeguards and security requirements, as well as a review of information provided by the intelligence community, the Commission has determined that certain additional security measures (ASMs) are required to address the current threat environment, in a consistent manner throughout the nuclear ISFSI community. Therefore, the Commission is imposing requirements, as set forth in Attachments 1 and 2 of this Order, on all licensees of these facilities. These requirements, which supplement existing regulatory requirements, will provide the Commission with reasonable assurance that the public health and safety, and the environment, continue to be adequately protected, and that the common defense and security continue to be adequately protected, in the current threat environment. These requirements will remain in effect until the Commission determines otherwise.

The Commission recognizes that licensees may have already initiated many of the measures set forth in Attachments 1 and 2 to this Order, in response to previously issued Advisories, or on their own. It also recognizes that some measures may not be possible or necessary at some sites, or may need to be tailored to accommodate the specific circumstances existing at Wolf Creek's facility, to achieve the intended objectives and avoid any unforeseen effect on the safe storage of spent fuel.

Although the ASMs implemented by licensees in response to the Safeguards and Threat Advisories have been sufficient to promote the common defense and security and to provide

reasonable assurance of adequate protection of public health and safety, in light of the continuing threat environment, the Commission concludes that these actions should be embodied in an Order, consistent with the established regulatory framework.

To provide assurance that Wolf Creek is implementing prudent measures to achieve a consistent level of protection to address the current threat environment, Wolf Creek's general license issued pursuant to 10 CFR 72.210 shall be modified to include the requirements identified in Attachments 1 and 2 to this Order. In addition, pursuant to 10 CFR 2.202, I find that, in light of the common defense and security circumstances described above, the public health, safety, and interest require that this Order be effective immediately.

IV

Accordingly, pursuant to Sections 53, 103, 104, 147, 149, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the NRC's regulations in 10 CFR 2.202 and 10 CFR parts 50, 72, and 73, *It is hereby ordered, effective immediately, that your general license is modified as follows:*

A. Wolf Creek shall comply with the requirements described in Attachments 1 and 2 to this Order, except to the extent that a more stringent requirement is set forth in the Wolf Creek Generating Station's physical security plan. Wolf Creek shall demonstrate its ability to comply with the requirements in Attachments 1 and 2 to the Order no later than 365 days from the date of this Order or 90 days before the first day that spent fuel is initially placed in the ISFSI, whichever is earlier. Wolf Creek must implement these requirements before initially placing spent fuel in the ISFSI. Additionally, Wolf Creek must receive written verification from the NRC (Office of Nuclear Material Safety and Safeguards) that it has adequately demonstrated compliance with these requirements before initially placing spent fuel in the ISFSI.

B. 1. Wolf Creek shall, within twenty (20) days of the date of this Order, notify the Commission: (1) If it is unable to comply with any of the requirements described in Attachments 1 and 2; (2) if compliance with any of the requirements is unnecessary, in its specific circumstances; or (3) if implementation of any of the requirements would cause Wolf Creek to be in violation of the provisions of any Commission regulation or the facility license. The notification shall provide Wolf Creek's justification for seeking relief from, or variation of, any specific requirement.

2. If Wolf Creek considers that implementation of any of the requirements described in Attachments 1 and 2 to this Order would adversely impact the safe storage of spent fuel, Wolf Creek must notify the Commission, within twenty (20) days of this Order, of the adverse safety impact, the basis for its determination that the requirement has an adverse safety impact, and either a proposal for achieving the same objectives specified in Attachments 1 and 2 requirements in question, or a schedule for modifying the facility, to address the adverse safety condition. If neither approach is appropriate, Wolf Creek must supplement its response to Condition B.1 of this Order to identify the condition as a requirement with which it cannot comply, with attendant justifications, as required under Condition B.1.

C. 1. Wolf Creek shall, within twenty (20) days of this Order, submit to the Commission a schedule for achieving compliance with each requirement described in Attachments 1 and 2.

2. Wolf Creek shall report to the Commission when it has achieved full compliance with the requirements described in Attachments 1 and 2.

D. All measures implemented or actions taken in response to this Order shall be maintained until the Commission determines otherwise.

Wolf Creek's response to Conditions B.1, B.2, C.1, and C.2, above, shall be submitted in accordance with 10 CFR 72.4. In addition, submittals and documents produced by Wolf Creek as a result of this Order, that contain Safeguards Information as defined by 10 CFR 73.22, shall be properly marked and handled, in accordance with 10 CFR 73.21 and 73.22.

The Director, Office of Nuclear Material Safety and Safeguards, may, in writing, relax or rescind any of the above conditions, for good cause.

V

In accordance with 10 CFR 2.202, Wolf Creek must, and any other person adversely affected by this Order may, submit an answer to this Order within 20 days of its publication in the **Federal Register**. In addition, Wolf Creek and any other person adversely affected by this Order may request a hearing on this Order within 20 days of its publication in the **Federal Register**. Where good cause is shown, consideration will be given to extending the time to answer or request a hearing. A request for extension of time must be made, in writing, to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and include a statement of good cause for the extension.

The answer may consent to this Order. If the answer includes a request for a hearing, it shall, under oath or affirmation, specifically set forth the matters of fact and law on which Wolf Creek relies and the reasons as to why the Order should not have been issued. If a person other than Wolf Creek requests a hearing, that person shall set forth with particularity the manner in which his/her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-filing rule (72 FR 49139, August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-filing process requires participants to submit and serve all adjudicatory documents electronically, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at *https://www.nrc.gov/site-help/e-submittals.html.* Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the

Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public website at *https://www.nrc.gov/site-help/e-submittals/getting-started.html.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submission is available on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. eastern time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC website at *http://www.nrc.gov/site-help/e-submittals.html,* by email at *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., eastern time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary of the Commission, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the Commission, or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

If a hearing is requested by Wolf Creek or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), Wolf Creek may, in addition to requesting a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the grounds that the Order, including the need for immediate effectiveness, is not based on adequate evidence, but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions as specified in Section III shall be final twenty (20) days from the date this Order is published in the **Federal Register**, without further Order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions of this Order, as specified in Section III, shall be final when the extension expires, if a hearing request has not been received. AN ANSWER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER. THIS ORDER.

Dated: July 22, 2020.

For the Nuclear Regulatory Commission.

John W. Lubinski, Director,
Office of Nuclear Material Safety and Safeguards.

Attachment 1—Additional Security Measures (ASMs) for Physical Protection of Dry Independent Spent Fuel Storage Installations (ISFSIs) contains Safeguards Information and is not included in this **Federal Register** Notice.

Attachment 2—Additional Security Measures for Access Authorization and Fingerprinting at Independent Spent Fuel Storage Installations, dated July 2, 2020.

A. General Basis Criteria

1. These additional security measures (ASMs) are established to delineate an independent spent fuel storage installation (ISFSI) licensee's responsibility to enhance security measures related to authorization for unescorted access to the protected area of an ISFSI in response to the current threat environment.

2. Licensees whose ISFSI is collocated with a power reactor may choose to comply with the U.S. Nuclear Regulatory Commission (NRC)-approved reactor access authorization program for the associated reactor as an alternative means to satisfy the provisions of sections B through G below. Otherwise, licensees shall comply with the access authorization and fingerprinting requirements of section B through G of these ASMs.

3. Licensees shall clearly distinguish in their 20-day response which method they intend to use in order to comply with these ASMs.

B. Additional Security Measures for Access Authorization Program

1. The licensee shall develop, implement and maintain a program, or enhance its existing program, designed to ensure that persons granted unescorted access to the protected area of an ISFSI are trustworthy and reliable and do not constitute an unreasonable risk to the public health and safety for the common defense and security, including a potential to commit radiological sabotage.

a. To establish trustworthiness and reliability, the licensee shall develop, implement, and maintain procedures for conducting and completing background investigations, prior to granting access. The scope of background investigations must address at least the past three years and, as a minimum, must include:

i. Fingerprinting and a Federal Bureau of Investigation (FBI) identification and criminal history records check (CHRC). Where an applicant for unescorted access has been previously fingerprinted with a favorably completed CHRC, (such as a CHRC pursuant to compliance with orders for access to safeguards information) the licensee may accept the results of that CHRC, and need not submit another set of fingerprints, provided the CHRC was completed not more than three years from the date of the application for unescorted access.

ii. Verification of employment with each previous employer for the most recent year from the date of application.

iii. Verification of employment with an employer of the longest duration during any calendar month for the remaining next most recent two years.

iv. A full credit history review.

v. An interview with not less than two character references, developed by the investigator.

vi. A review of official identification (*e.g.,* driver's license; passport; government identification; state-, province-, or country-of-birth issued certificate of birth) to allow comparison of personal information data provided by the applicant. The licensee shall maintain a photocopy of the identifying document(s) on file, in accordance with ''Protection of Information,'' in Section G of these ASMs.

vii. Licensees shall confirm eligibility for employment through the regulations of the U.S. Department of Homeland Security, U.S. Citizenship and Immigration Services, and shall verify and ensure, to the extent possible, the accuracy of the provided social security number and alien registration number, as applicable.

b. The procedures developed or enhanced shall include measures for confirming the term, duration, and character of military service for the past three years, and/or academic enrollment and attendance in lieu of employment, for the past five years.

c. Licensees need not conduct an independent investigation for individuals employed at a facility who possess active ''Q'' or ''L'' clearances or possess another active U.S. Government-granted security clearance (*i.e.,* Top Secret, Secret, or Confidential).

d. A review of the applicant's criminal history, obtained from local criminal justice resources, may be included in addition to the FBI CHRC, and is encouraged if the results of the FBI CHRC, employment check, or credit check disclose derogatory information. The scope of the applicant's local criminal history check shall cover all residences of record for the past three years from the date of the application for unescorted access.

2. The licensee shall use any information obtained as part of a CHRC solely for the purpose of determining an individual's suitability for unescorted access to the protected area of an ISFSI.

3. The licensee shall document the basis for its determination for granting or denying access to the protected area of an ISFSI.

4. The licensee shall develop, implement, and maintain procedures for updating background investigations for persons who are applying for reinstatement of unescorted access. Licensees need not conduct an independent reinvestigation for individuals who possess active ''Q'' or ''L'' clearances or possess another active U.S. Government granted security clearance, *i.e.,* Top Secret, Secret or Confidential.

5. The licensee shall develop, implement, and maintain procedures for reinvestigations of persons granted unescorted access, at intervals not to exceed five years. Licensees need not conduct an independent reinvestigation for individuals employed at a facility who possess active ''Q'' or ''L'' clearances or possess another active U.S. Government granted security clearance, *i.e.,* Top Secret, Secret or Confidential.

6. The licensee shall develop, implement, and maintain procedures designed to ensure that persons who have been denied unescorted access authorization to the facility are not allowed access to the facility, even under escort.

7. The licensee shall develop, implement, and maintain an audit program for licensee and contractor/vendor access authorization programs that evaluate all program elements and include a person knowledgeable and practiced in access authorization program performance objectives to assist in the overall assessment of the site's program effectiveness.

C. Fingerprinting Program Requirements

1. In a letter to the NRC, the licensee must nominate an individual who will review the results of the FBI CHRCs to make trustworthiness and reliability determinations for unescorted access to an ISFSI. This individual, referred to as the ''reviewing official,'' must be someone who requires unescorted access to the ISFSI. The NRC will review the CHRC of any individual nominated to perform the reviewing official function. Based on the results of the CHRC, the NRC staff will determine whether this individual may have access. If the NRC determines that the nominee may not be granted such access, that individual will be prohibited from obtaining access.[1] Once the NRC approves a reviewing official, the reviewing official is the only individual permitted to make access determinations for other individuals who have been identified by the licensee as having the need for unescorted access to the ISFSI, and have been fingerprinted and have had a CHRC in accordance with these ASMs. The reviewing official can only make access determinations for other individuals, and therefore cannot approve other individuals to act as reviewing officials. Only the NRC can approve a reviewing official. Therefore, if the licensee wishes to have a new or additional reviewing official, the NRC must approve that individual before he or she can act in the capacity of a reviewing official.

2. No person may have access to Safeguards Information (SGI) or unescorted access to any facility subject to NRC regulation, if the NRC has determined, in accordance with its administrative review process based on fingerprinting and an FBI identification and CHRC, that the person may not have access to SGI or unescorted access to any facility subject to NRC regulation.

3. All fingerprints obtained by the licensee under this Order, must be submitted to the Commission for transmission to the FBI.

4. The licensee shall notify each affected individual that the fingerprints will be used to conduct a review of his/her criminal history record and inform

[1] The NRC's determination of this individual's unescorted access to the ISFSI, in accordance with the process, is an administrative determination that is outside the scope of the Order.

the individual of the procedures for revising the record or including an explanation in the record, as specified in the ''Right To Correct and Complete Information,'' in section F of these ASMs.

5. Fingerprints need not be taken if the employed individual (*e.g.,* a licensee employee, contractor, manufacturer, or supplier) is relieved from the fingerprinting requirement by 10 CFR 73.61, has a favorably adjudicated U.S. Government CHRC within the last five (5) years, or has an active Federal security clearance. Written confirmation from the Agency/employer who granted the Federal security clearance or reviewed the CHRC must be provided to the licensee. The licensee must retain this documentation for a period of three years from the date the individual no longer requires access to the facility.

D. Prohibitions

1. A licensee shall not base a final determination to deny an individual unescorted access to the protected area of an ISFSI solely on the basis of information received from the FBI involving: an arrest more than one (1) year old for which there is no information of the disposition of the case, or an arrest that resulted in dismissal of the charge, or an acquittal.

2. A licensee shall not use information received from a CHRC obtained pursuant to this Order in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall the licensee use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, sex, or age.

E. Procedures for Processing Fingerprint Checks

1. For the purpose of complying with this Order, licensees shall, using an appropriate method listed in 10 CFR 73.4, submit to the NRC's Division of Physical and Cyber Security Policy, Mail Stop T–08B20M, one completed, legible standard fingerprint card (Form FD–258, ORIMDNRCOOOZ) or, where practicable, other fingerprint records for each individual seeking unescorted access to an ISFSI, to the Director of the Division of Physical and Cyber Security Policy, marked for the attention of the Criminal History Check Section. Copies of these forms may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by email to *mailsvc.resource@nrc.gov.* Practicable alternative formats are set forth in 10 CFR 73.4. The licensee shall establish procedures to ensure that the quality of the fingerprints taken results in minimizing the rejection rate of fingerprint cards because of illegible or incomplete cards.

2. The NRC will review submitted fingerprint cards for completeness. Any Form FD–258 fingerprint record containing omissions or evident errors will be returned to the licensee for corrections. The fee for processing fingerprint checks includes one re-submission if the initial submission is returned by the FBI because the fingerprint impressions cannot be classified. The one free re-submission must have the FBI Transaction Control Number reflected on the re-submission. If additional submissions are necessary, they will be treated as initial submittals and will require a second payment of the processing fee.

3. Fees for processing fingerprint checks are due upon application. The licensee shall submit payment of the processing fees electronically. To be able to submit secure electronic payments, licensees will need to establish an account with *Pay.Gov* (*https://www.pay.gov*). To request an account, the licensee shall send an email to *paygo@nrc.gov.* The email must include the licensee's company name, address, point of contact (POC), POC email address, and phone number. The NRC will forward the request to *Pay.Gov*; who will contact the licensee with a password and user lD. Once the licensee has established an account and submitted payment to *Pay.Gov*, they shall obtain a receipt. The licensee shall submit the receipt from *Pay.Gov* to the NRC along with fingerprint cards. For additional guidance on making electronic payments, contact the Reactor Security Branch, Division of Physical and Cyber Security Policy, at (301) 415–7513. Combined payment for multiple applications is acceptable. The application fee (currently $10) is the sum of the user fee charged by the FBI for each fingerprint card or other fingerprint record submitted by the NRC on behalf of a licensee, and an NRC processing fee, which covers administrative costs associated with NRC handling of licensee fingerprint submissions. The Commission will directly notify licensees who are subject to this regulation of any fee changes.

4. The Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for CHRCs, including the FBI fingerprint record.

F. Right To Correct and Complete Information

1. Prior to any final adverse determination, the licensee shall make available to the individual the contents of any criminal history records obtained from the FBI for the purpose of assuring correct and complete information. Written confirmation by the individual of receipt of this notification must be maintained by the licensee for a period of one (1) year from the date of notification.

2. If, after reviewing the record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, or update the alleged deficiency, or to explain any matter in the record, the individual may initiate challenge procedures. These procedures include either direct application by the individual challenging the record to the agency (*i.e.,* law enforcement agency) that contributed the questioned information, or direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Assistant Director, Federal Bureau of Investigation Identification Division, Washington, DC 20537–9700 (as set forth in 28 CFR 16.30 through 16.34). In the latter case, the FBI forwards the challenge to the agency that submitted the data and requests that agency to verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. The licensee must provide at least 10 days for an individual to initiate an action challenging the results of a FBI CHRC after the record is made available for his/her review. The licensee may make a final access determination based on the criminal history record only upon receipt of the FBI's ultimate confirmation or correction of the record. Upon a final adverse determination on access to an ISFSI, the licensee shall provide the individual its documented basis for denial. Access to an ISFSI shall not be granted to an individual during the review process.

G. Protection of Information

1. The licensee shall develop, implement, and maintain a system for personnel information management with appropriate procedures for the protection of personal, confidential information. This system shall be designed to prohibit unauthorized access to sensitive information and to

prohibit modification of the information without authorization.

2. Each licensee who obtains a criminal history record on an individual pursuant to this Order shall establish and maintain a system of files and procedures, for protecting the record and the personal information from unauthorized disclosure.

3. The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his/her representative, or to those who have a need to access the information in performing assigned duties in the process of determining suitability for unescorted access to the protected area of an ISFSI. No individual authorized to have access to the information may re-disseminate the information to any other individual who does not have the appropriate need to know.

4. The personal information obtained on an individual from a CHRC may be transferred to another licensee if the gaining licensee receives the individual's written request to re-disseminate the information contained in his/her file, and the gaining licensee verifies information such as the individual's name, date of birth, social security number, sex, and other applicable physical characteristics for identification purposes.

5. The licensee shall make criminal history records, obtained under this section, available for examination by an authorized representative of the NRC to determine compliance with the regulations and laws.

[FR Doc. 2020–16370 Filed 7–28–20; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2020–203 and CP2020–230]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 31, 2020.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2020–203 and CP2020–230; *Filing Title:* USPS Request to Add Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contract 7 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 23, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Gregory Stanton; *Comments Due:* July 31, 2020.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2020–16407 Filed 7–28–20; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Board of Governors; Sunshine Act Meetings

TIME AND DATE: Thursday, August 6, 2020, at 11:00 a.m.; and Friday, August 7, 2020, at 9:00 a.m.

PLACE: Washington, DC, at U.S. Postal Service Headquarters, 475 L'Enfant Plaza SW, in the Benjamin Franklin Room.

STATUS: Thursday, August 6, 2020, at 11:00 a.m.—Closed; Friday, August 7, 2020, at 9:00 a.m.—Open.

MATTERS TO BE CONSIDERED:

Thursday, August 6, 2020, at 11:00 a.m. (Closed)

1. Strategic Issues.
2. Financial and Operational Matters.
3. Compensation and Personnel Matters.
4. Administrative Items.

Friday, August 7, 2020, at 9:00 a.m. (Open)

1. Remarks of the Chairman of the Board of Governors.
2. Remarks of the Postmaster General and CEO.
3. Approval of Minutes of Previous Meetings.
4. Committee Reports.
5. Quarterly Financial Report.
6. Quarterly Service Performance Report.
7. Approval of Tentative Agenda for November Meetings.

CONTACT PERSON FOR MORE INFORMATION: Katherine Sigler, acting Secretary of the Board, U.S. Postal Service, 475 L'Enfant

Plaza SW, Washington, DC 20260–1000. Telephone: (202) 268–4800.

Michael J. Elston,

Secretary.

[FR Doc. 2020–16502 Filed 7–27–20; 11:15 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

International Product Change—Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Agreement: Postal Service™

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: *Date of notice:* July 29, 2020.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 23, 2020, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contract 7 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2020–203 and CP2020–230.

Joshua J. Hofer,

Attorney, Federal Compliance.

[FR Doc. 2020–16439 Filed 7–28–20; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89389; File No. SR–CBOE–2020–067]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 6.7 Concerning Off-Floor Transfers

July 23, 2020.

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 July 17, 2020, 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 and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] 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 Rule 6.7. The text of the proposed rule change is provided below.

(additions are *italicized;* deletions are [bracketed])

* * * * *

Rules of Cboe Exchange, Inc.

* * * * *

Rule 6.7. Off-Floor Transfers of Positions

(a)–(c) No change.

(d) *Prior Written Notice.* A Trading Permit Holder(s) and its Clearing Trading Permit Holder(s) (to the extent that the Trading Permit Holder is not self-clearing) must submit to the Exchange, in a manner determined by the Exchange, written notice prior to effecting an off-floor transfer from or to the account(s) of a Trading Permit Holder(s), except that notification is not required for transfers [to correct errors]*effected* pursuant to subparagraph (a)(1) *or (a)(2)* of this Rule.

(1) The notice must indicate (A) the Exchange-listed options positions to be transferred, (B) the nature of the transaction, (C) the enumerated provision(s) under paragraph (a) pursuant to which the positions are being transferred, (D) the name of the counterparty(ies), (E) the anticipated transfer date, (F) the method for determining the transfer price under paragraph [(d) below]*(c) above,* and (G) any other information requested by the Exchange.

* * * * *

(g) *Routine, Recurring Transfers.* The off-floor transfer procedure set forth in this Rule is intended to facilitate non-routine, non-recurring movements of positions[. The off-floor transfer procedure] *and* is not to be used repeatedly or routinely[in circumvention of the normal auction market process]*, except for transfers between accounts of the same Person pursuant to subparagraph (a)(2). The off-floor transfer procedure may not be used in circumvention of the normal auction process.*

* * * * *

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.

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

Rule 6.7 describes exceptions to the prohibition against off-floor transactions set forth in Rule 5.12, subject to certain conditions. The exception in Rule 6.7(a)(2) provides that off-floor transfers of positions are permissible if from one account to another account where no change in ownership is involved (*i.e.,* accounts of the same Person),[5] provided the accounts are not in separate aggregation units or otherwise subject to information barrier or account segregation requirements. These transfers are subject to, among other things, the requirement to submit prior written notice of the transfers to the Exchange pursuant to paragraph (d) and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] Rule 1.1 defines ''Person'' as an individual, partnership (general or limited), joint stock company, corporation, limited liability company, trust, or unincorporated organization, or any governmental entity or agency or political subdivision thereof.

the restriction on effecting these transfers repeatedly or routinely.

The proposed rule change excepts off-floor position transfers effected pursuant to Rule 6.7(a)(2) from the prior written notice requirement in paragraph (d) and from repeated, recurring use restriction in paragraph (g). Off-floor position transfers pursuant to Rule 6.7(a)(2) do not involve a change in ownership. In other words, such transfers may only occur between the same individual or legal entity. These types of transfers are merely transfers of positions from one account to another, both of which accounts are attributable to the same individual or legal entity, and thus the transferred option positions will continue to be attributable to the same Person. A market participant effecting an off-floor position transfer pursuant to Rule 6.7(a)(2) is analogous to an individual transferring funds from a checking account to a savings account, or from an account at one bank to an account at another bank—the money still belongs to the same person, who is just holding it in a different account for personal financial reasons.

Because there is no change in ownership of positions transferred pursuant to Rule 6.7(a)(2), the Exchange believes it is appropriate to permit them to occur as routinely and repeatedly as a market participant would like. These transfers will continue to be subject to the prohibition on netting set forth in Rule 6.7(b), and thus may not result in the closing of any positions. While the off-floor position transfers permitted by Rule 6.7 were intended to accommodate non-routine and non-recurring transfers, the Exchange believes permitting routine, recurring off-floor position transfers that do not result in a change in ownership or reduction in open interest is consistent with the purpose of not being used to circumvent the normal auction purpose. Additionally, given that these transfers may occur on a regular basis in accordance with a market participants' business needs and procedures, the Exchange believes prior written notice would be onerous and would not serve any purpose given the lack of change in ownership and in open interest. The Exchange believes this will provide market participants with additional flexibility to structure their option position accounts as they believe is appropriate and move their positions between accounts as they deem necessary and appropriate for their business and trading needs, including for risk management purposes.

The proposed rule change also corrects an erroneous cross-reference in Rule 6.7(d)(1), as the method for determining the transfer price is in paragraph (c) rather than paragraph (d) of Rule 6.7.

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 the Section 6(b)(5)[8] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule change will 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 because it will provide market participants with a more efficient process to transfer open positions between their own accounts in accordance with their own business and trading needs, including to respond to then-current market conditions. Because these transfers would not result in a change in ownership or a reduction in open interest, the Exchange believes the proposed rule change remains consistent with the purpose of Rule 6.7, which was to prohibit use of the off-floor transfer procedure in circumvention of the normal auction process, as the normal auction process involves the opening or closing of positions through a transaction among multiple market participants. Market participants may maintain different accounts for a variety of reasons, such as the structure of their businesses, the manner in which they trade, their risk management procedures, and for capital purposes. Given that these transfers may occur on a regular basis in accordance with a market participants' business needs and procedures, the Exchange believes prior written notice would be onerous and would not serve any purpose given the lack of change in ownership and in open interest. Therefore, the proposed rule change will benefit investors by permitting market participants to manage the open positions in their accounts in a manner consistent with their businesses.

The Exchange recognizes the numerous benefits of executing options transactions on an exchange, including price transparency, potential price improvement, and a clearing guarantee. However, the Exchange believes it is appropriate to permit position transfers among accounts of the same individual or legal entity where there is no impact on open interest to occur off the exchange, as these benefits are inapplicable to those transfers. These transfers have a narrow scope and are intended to permit market participants to achieve their own business needs. These transfers are not intended to be a competitive trading tool. There is no need for price discovery or improvement, as the transfer merely moves positions to different accounts for the same Person and does not open or close any positions. These transfers will result in no change in ownership. The transactions that resulted in the open positions to be transferred pursuant to Rule 6.7(a)(2) were already guaranteed by a clearing member of The Options Clearing Corporation (''OCC''), and the positions may not be closed pursuant to the transfer and will continue to be subject to OCC rules, as they will continue to be held in an account with an OCC clearing member.

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 proposed rule change is not intended to address competitive issues. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed rule change will apply to all market participants in the same manner. All market participants will be able to effect off-floor position transfers pursuant to Rule 6.7(a)(2) on a recurring or routine basis without providing the Exchange with notice of such transfers. The Exchange does not

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *Id.*

believe the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because it relates solely to the notice required for off-floor transfers that may occur today, and the frequency with which those transfers may occur. These transfers will continue to not result in a change in ownership or netting, and thus will have no impact on outstanding option positions.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [9] and Rule 19b–4(f)(6) thereunder.[10] Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and Rule 19b–4(f)(6) [12] 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–2020–067 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–2020–067. 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–CBOE–2020–067 and should be submitted on or before August 19, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–16371 Filed 7–28–20; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89388; File No. SR–NYSENAT–2020–23]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.37 To Add the Data Source for MEMX

July 23, 2020.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 14, 2020, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.37 to update the Exchange's source of data feeds from MEMX LLC (''MEMX'') for purposes of order handling, order execution, order routing, and regulatory compliance. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

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 update and amend the use of data feeds table in Rule 7.37, which sets forth on a market-by-market basis the specific securities information processor (''SIP'') and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks related to each of those functions. Specifically, the Exchange proposes to amend the table in Rule 7.37(d) to specify that, with respect to MEMX, the Exchange will receive the SIP feed as its primary source of data for order handling, order execution, order routing, and regulatory compliance. The Exchange will not have a secondary source for data from MEMX.

The Exchange proposes that this proposed rule change would be operative on the day that MEMX launches operations as an equities exchange, which is currently expected on September 4, 2020.[4]

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Section 6(b)(5),[6] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes its proposal to amend the table in Rule 7.37(d) to update the data feed source for the MEMX will ensure that Rule 7.37 correctly identifies and publicly states on a market-by-market basis all of the specific SIP and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks for each of those functions. The proposed rule change also removes impediments to and perfects the mechanism of a free and open market and protects investors and the public interest by providing additional specificity, clarity, and transparency in the Exchange's rules.

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 proposed change is not designed to address any competitive issue, but rather would provide the public and market participants with up-to-date information about the data feeds the Exchange will use for the handling, execution, and routing of orders, as well as for regulatory compliance.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[7] and Rule 19b–4(f)(6) thereunder.[8] Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; or (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

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)[9] 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–NYSENAT–2020–23 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSENAT–2020–23. 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–NYSENAT–2020–23, and should be submitted on or before August 19, 2020.

[4] *See https://memx.com/memx-timeline-update-launch-set-for-september-4th/.*

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(3)(A)(iii).

[8] 17 CFR 240.19b–4(f)(6).

[9] 15 U.S.C. 78s(b)(2)(B).

[10] 17 CFR 200.30–3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–16374 Filed 7–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89381; File No. SR–FINRA–2020–021]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 2360 (Options) To Increase Position Limits on Options on Certain Exchange-Traded Funds

July 22, 2020.

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 July 14, 2020, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. 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 the Substance of the Proposed Rule Change

FINRA is proposing to amend Rule 2360 (Options) to increase the position and exercise limits for conventional options on certain exchange-traded funds (''ETFs'').

Below is the text of the proposed rule change. Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

2360. Options

(a) No Change.

(b) Requirements

(1) through (2) No Change.

(3) Position Limits

(A) Stock Options—

(i) through (ii) No Change.

(iii) Conventional Equity Options.

a. For purposes of this paragraph (b), standardized equity option contracts of the put class and call class on the same side of the market overlying the same security shall not be aggregated with conventional equity option contracts or FLEX Equity Option contracts overlying the same security on the same side of the market. Conventional equity option contracts of the put class and call class on the same side of the market overlying the same security shall be subject to a position limit of:

1. through 5. No Change.

6. for selected conventional options on exchange-traded funds (''ETF''), the position limits are listed in the chart below:

Security underlying option	Position limit (contracts)
The DIAMONDS Trust (DIA)	300,000
The Standard and Poor's Depositary Receipts Trust (SPY)	[1,800,000]*3,600,000*
The iShares Russell 2000 ETF (IWM)	1,000,000
The PowerShares QQQ Trust (QQQ)	1,800,000
The iShares MSCI Emerging Markets ETF (EEM)	1,000,000
iShares China Large-Cap ETF (FXI)	[500,000]*1,000,000*
iShares MSCI EAFE ETF (EFA)	[500,000]*1,000,000*
iShares MSCI Brazil Capped ETF (EWZ)	500,000
iShares 20+ Year Treasury Bond Fund ETF (TLT)	500,000
iShares MSCI Japan ETF (EWJ)	500,000
iShares iBoxx High Yield Corporate Bond Fund (HYG)	*500,000*
Financial Select Sector SPDR Fund (XLF)	*500,000*

b. No Change.

(B) through (D) No Change.

(4) through (24) No Change.

(c) No Change.

Supplementary Material

.01 through .03 No Change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA 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. FINRA 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

FINRA Rule 2360(b)(3)(A) imposes a position limit on the number of equity options contracts in each class on the same side of the market that can be held or written by a member, a person associated with a member, or a customer or a group of customers acting in concert. Position limits are intended to prevent the establishment of options positions that can be used to manipulate or disrupt the underlying market or might create incentives to manipulate or disrupt the underlying market so as to benefit the options position. In addition, position limits serve to reduce the potential for disruption of the options market itself, especially in illiquid options classes.[4] This consideration has been balanced by the concern that the limits ''not be established at levels that are so low as to discourage participation in the options market by institutions and other investors with substantial hedging needs or to prevent specialists and market makers from adequately

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] *See* Securities Exchange Act Release No. 40969 (January 22, 1999), 64 FR 4911, 4912–4913 (February 1, 1999) (Order Approving File No. SR–CBOE–98–23) (citing H.R. No. IFC–3, 96th Cong., 1st Sess. at 189–91 (Comm. Print 1978)).

meeting their obligations to maintain a fair and orderly market.'' [5]

Rule 2360(b)(3)(A)(i) does not independently establish a position limit for standardized equity options. Rather, the position limit established by the rules of an options exchange for a particular equity option is the applicable position limit for purposes of Rule 2360.[6] Rule 2360(b)(3)(A)(iii) provides that conventional equity options [7] are subject to a basic position limit of 25,000 contracts or a higher tier for conventional option contracts on securities that underlie exchange-traded options qualifying for such higher tier as determined by the rules of the options exchanges. In addition, FINRA lists position limits for options on securities that have higher position limits—currently, only the ETFs listed in Rule 2360(b)(3)(A)(iii)a.6.—that also generally mirror the options exchange position limits. At this time, FINRA proposes to conform its conventional options position limits to the Cboe Exchange, Inc.'s (''Cboe'') recent amendments that increased the position limit options due to an ongoing increase in demand in options on the following ETFs: The Standard and Poor's Depositary Receipts Trust (''SPY''), iShares MSCI EAFE ETF (''EFA''), iShares China Large-Cap ETF (''FXI''), iShares iBoxx High Yield Corporate Bond Fund (''HYG''), and Financial Select Sector SPDR Fund (''XLF'' collectively, with the aforementioned ETFs, the ''Underlying ETFs'').[8]

The proposed rule change would amend the table provided in Rule 2360(b)(3)(A)(iii)a.6. as follows:

- The position limits for options on SPY would be increased from 1,800,000 contracts to 3,600,000 contracts;
- The position limit for options on EFA would be increased from 500,000 contracts to 1,000,000 contracts; and
- The position limit for options on FXI would be increased from 500,000 contracts to 1,000,000 contracts.

In addition, the proposed rule change would add to the table provided in Rule 2360(b)(3)(A)(iii)a.6. as follows, with the effect of each ETF being increased from the current position limit of 250,000 contracts:

- The position limit for options on HYG would be increased to 500,000 contracts; and
- The position limit for options on XLF would be increased to 500,000 contracts.

FINRA notes the proposed position limits on EFA and FXI are consistent with existing position limits for options on the iShares Russell 2000 ETF (''IWM'') and the iShares MSCI Emerging Markets ETF (''EEM''), and the proposed limits for options on XLF and HYG are consistent with current position limits for options on the iShares MSCI Brazil Capped ETF (''EWZ''), iShares 20+Year Treasury Bond Fund ETF (''TLT''), and iShares MSCI Japan ETF (''EWJ'').

In support of the proposed rule change, as noted by Cboe, position limits are determined by the option exchange's rules.[9] The ETFs that underlie options subject to the proposed rule change are highly liquid, and are based on a broad set of highly liquid securities and other reference assets. The above listed ETFs are listed on various national securities exchanges and meet their listing standards.

In supporting the proposed position limit increases, FINRA considered both liquidity of the Underlying ETFs and the component securities of the Underlying ETFs, as well as the availability of economically equivalent products to the overlying options and their respective position limits. For instance, some of the Underlying ETFs are based upon broad-based indices that underlie cash-settled options, and therefore the options on the Underlying ETFs are economically equivalent to the options on those indices, which have no position limits. Other Underlying ETFs are based upon broad-based indices that underlie cash-settled options with position limits reflecting notional values that are larger than current position limits for options on the ETF analogues. For indexes that are tracked by an Underlying ETF but on which there are no options listed, FINRA believes, based on the liquidity, depth and breadth of the underlying market of the components of the indexes, that each of the indexes referenced by the applicable ETFs would be considered a broad-based index under options exchange rules. Additionally, if in some cases certain position limits are appropriate for the options overlying comparable indexes or basket of securities that the Underlying ETFs track then those economically equivalent position limits should be appropriate for the options overlying the Underlying ETFs.

FINRA notes that Cboe has compiled the following trading statistics regarding shares of and exchange-traded options on the Underlying ETFs, as well as the component securities or components underlying the referenced index (as applicable): [10]

Product	ADV (ETF shares) (in millions)	ADV (option contracts)	Shares outstanding (ETFs) (in millions)	Fund market Cap (USD) (billion)	Total market cap of ETF components
SPY	70.3	2.8 million	968.7	312.9	29.3 trillion
FXI	26.1	196,600	106.8	4.8	28.0 trillion
EFA	25.1	155,900	928.2	64.9	19.3 trillion
HYG	20.0	193,700	216.6	19.1	906.4 billion
XLF	48.8	102,100	793.6	24.6	3.8 trillion

[5] *See supra* at 4913.

[6] *See e.g.,* Cboe Rule 8.30; ISE Options 9 Section 13; NASDAQ PHLX Options 9 Section 13; NYSE American Rule 904; NYSE Arca Rule 6.8–0; MIAX Rule 307; BOX Rule 3120 and IM–3120–2; NASDAQ Options 9 Section 13; BX Options 9 Section 13; and BZX Rule 18.7.

[7] Conventional options are over-the-counter options and are defined in Rule 2360(a)(9) as ''(A) any option contract not issued, or subject to issuance, by The Options Clearing Corporation; or (B) an OCC Cleared OTC Option.''

[8] *See* Securities Exchange Act Release No. 88768 (April 29, 2020), 85 FR 26736 (May 5, 2020) (Order Granting Approval of File No. SR–CBOE–2020–015). *See also* Securities Exchange Act Release No. 88893 (May 18, 2020), 85 FR 31239 (May 22, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–MIAX–2020–10) and Securities Exchange Act Release No. 88894 (May 18, 2020), 85 FR 31267 (May 22, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–BOX–2020–13).

[9] *See e.g.,* Cboe Rule 8.30, Interpretation and Policy .02.

[10] *See* note 8. As noted above, the position limit for standardized options under Rule 2360 is the limit established by an exchange on which the option trades. The position limit for conventional options under Rule 2360 generally mirrors the options exchange position. The proposed rule change would maintain consistent position limits between standardized and conventional options on the same underlying security. FINRA believes that the Cboe reasoning regarding the increase to standardized options position limits applies equally to increasing the position limit for conventional options.

Further, Cboe has collected the same trading statistics, where applicable, as above regarding a sample of other ETFs, as well as the current position limits for options on such ETFs, to draw comparisons in support of proposed position limit increases for options on a number of the Underlying ETFs:

Product	ADV (ETF shares) (in millions)	ADV (option contracts)	Shares outstanding (ETFs) (in millions)	Fund market cap (USD) (billion)	Total market cap of ETF components	Current position limit
QQQ	30.2	670,200	410.3	88.7	10.1 trillion	1,800,000
EWZ	26.7	186,500	233	11.3	234.6 billion	500,000
TLT	9.6	95,200	128.1	17.5	N/A	500,000
EWJ	7.2	5,700	236.6	14.2	3 trillion	500,000

FINRA agrees with Cboe that, overall, the liquidity in the shares of the Underlying ETFs and in the component securities of the Underlying ETFs, and in their overlying options, as well as the large market capitalizations and structure of each of the Underlying ETFs, support the proposal to increase the position limits for each option class. Given the robust liquidity and capitalization in the Underlying ETFs and in the component securities of the Underlying ETFs, FINRA believes the market capitalization of the underlying component securities of the applicable ETF is large enough to adequately absorb potential price movements that may be caused by large trades. The following analyses for the Underlying ETFs, which FINRA agrees with in support of the proposed rule change, as well as the statistics presented in support thereof, were presented by Cboe in their initial filing, which was approved by the Commission.

Specifically, Cboe notes that SPY tracks the performance of the S&P 500® Index, which is an index of diversified large cap U.S. companies.[11] It is composed of 505 selected stocks spanning over approximately 24 separate industry groups. The S&P 500® is one of the most commonly followed equity indices, and is widely considered to be the best indicator of stock market performance as a whole. SPY is one of the most actively traded ETFs, and, since 2017, its ADV has increased from approximately 64.6 million shares to 70.3 million shares by the end of 2019. Similarly, its ADV in options contracts has increased from 2.6 million to 2.8 million through 2019. As noted, the demand for options trading on SPY has continued to increase, however, the position limits have remained the same, which may have impacted growth in SPY option volume from 2017 through 2019. SPY shares are more liquid than PowerShares QQQ Trust (''QQQ'') shares, which is also currently subject to a position limit of 1,800,000 contracts. Specifically, SPY currently experiences over twice the ADV in shares and over four times the ADV in options than that of QQQ.

EFA tracks the performance of MSCI EAFE Index, which is composed of over 900 large and mid-cap securities across 21 developed markets, including countries in Europe, Australia and the Far East, excluding the U.S. and Canada.[12] From 2017 through 2019, ADV has grown significantly in shares of EFA and in options on EFA, from approximately 19.4 million shares in 2017 to 25.1 million through 2019, and from approximately 98,800 options contract in 2017 to 155,900 through 2019. Options are available on the MSCI EAFE Index (''MXEA''), the analogue index, which was previously subject to a position limit of 25,000 contracts (50,000 as proposed by Cboe and approved the Commission).[13] Using the notional value comparison of EFA's share price of $69.44 and MXEA's index level of 2036.94, approximately 29 EFA option contracts equal one MXEA option contract.[14] Based on the above comparison of notional values, a position limit for EFA options that would be economically equivalent to that of MXEA options equates to 725,000 contracts (previously) and 1,450,000 (for the Cboe proposed 50,000 contracts position limit increase for MXEA options that was approved by the Commission). Also, MXEA index options have an ADV of 594 options contracts, in which equate to an ADV of 17,226 EFA option contracts (as that is 29 times the size of 594). EFA options, which are more actively traded and held than MXEA options, are currently subject to a position limit of 500,000 options contracts despite their much higher ADV of approximately 155,900 options contracts.

FXI tracks the performance of the FTSE China 50 Index, which is composed of the 50 largest Chinese stocks.[15] FXI shares and options have also experienced increased liquidity since 2017, as ADV has grown from approximately 15.1 million shares in 2017 to 26.1 million through 2019, as well as approximately 71,900 options contracts in 2017 to 196,600 through 2019. Although there are currently no options on the FTSE China 50 Index listed for trading, the components of the FTSE China 50 Index, which can be used to create a basket of stocks that equate to the FXI ETF, currently have a market capitalization of approximately $28 trillion and FXI has a market capitalization of $4.8 billion (as indicated above), which are both large enough to absorb potential price movements caused by a large trade in FXI.

XLF invests in a wide array of financial service firms with diversified business lines ranging from investment management to commercial and investment banking. It generally corresponds to the price and yield performance of publicly traded equity securities of companies in the SPDR Financial Select Sector Index.[16] XLF experiences ADV in shares and in exchange-traded options (48.8 million shares and 102,100 options contracts) that is significantly greater than the ADV in shares and options for EWZ (26.7 million shares and 186,500 options contracts), TLT (9.6 million shares and 95,200 options contracts), and EWJ (7.2 million shares and 5,700 options contracts), each of which already have a position limit of 500,000 contracts—the proposed position limit

[11] *See* SPDR® S&P 500® ETF Trust, available at *https://www.ssga.com/us/en/individual/etfs/funds/spdr-sp-500-etf-trust-spy* (January 21, 2020).

[12] *See* iShares MSCI EAFE ETF, available at *https://www.ishares.com/us/products/239623/ishares-msci-eafe-etf* (February 10, 2020).

[13] *See* note 8. Cboe is proposing [sic] to raise the position limit on certain indexes. FINRA incorporates by reference the exchange position limits on indexes in FINRA Rule 2360(b)(3)(B) and accordingly does not need to propose any corresponding FINRA rule change.

[14] *See* note 8. The values were presented by Cboe in their initial filing, which was approved by the Commission.

[15] *See* iShares China Large-Cap ETF, available at *https://www.ishares.com/us/products/239536/ishares-china-largecap-etf* (February 10, 2020).

[16] *See* Select Sector SPDR ETFs, XLF, available at *http://www.sectorspdr.com/sectorspdr/sector/xlf* (January 15, 2020).

for XLF options. Although there are no options on the SPDR Financial Select Sector Index listed for trading, the components of the index, which can be used to create a basket of stocks that equate to the XLF ETF, currently have a market capitalization of $3.8 trillion (indicated above). Additionally, XLF has a market capitalization of $24.6 billion. Both of these are large enough to absorb potential price movements caused by a large trade in XLF.

Finally, HYG attempts to track the investment results of Markit iBoxx USD Liquid High Yield Index, which is composed of U.S. dollar-denominated, high-yield corporate bonds and is one of the most widely used high-yield bond ETFs.[17] HYG experiences significantly higher ADV in shares and exchange-traded options (20 million shares and 193,700 options contracts) than both TLT (9.6 million shares and 95,200 options contracts), and EWJ (7.2 million shares and 5,700 options contracts), which are currently subject to a position limit of 500,000 options contracts—the proposed limit for options on HYG. While HYG does not have an index option analogue listed for trading, FINRA agrees with Cboe's belief that HYG's market capitalization of $19.1 billion, and of $906.4 billion in component securities, is adequate to absorb a potential price movement that may be caused by large trades in HYG.

FINRA believes that increasing the position limits for conventional options subject to the proposed rule change would lead to a more liquid and competitive market for these options, which will benefit customers interested in these products.

Creation and Redemption for ETFs

FINRA believes that the creation and redemption process for ETFs will lessen the potential for manipulative activity with options on the Underlying ETFs. When an ETF provider wants to create more shares, it looks to an Authorized Participant (generally a market maker or other large financial institution) to acquire the securities the ETF is to hold. For instance, when an ETF is designed to track the performance of an index, the Authorized Participant can purchase all the constituent securities in the exact same weight as the index, then deliver those shares to the ETF provider. In exchange, the ETF provider gives the Authorized Participant a block of equally valued ETF shares, on a one-for-one fair value basis. The price is based on the net asset value, not the market value at which the ETF is trading. The creation of new ETF units can be conducted during an entire trading day, and is not subject to position limits. This process works in reverse where the ETF provider seeks to decrease the number of shares that are available to trade. The creation and redemption process, therefore, creates a direct link to the underlying components of the ETF, and serves to mitigate potential price impact of the ETF shares that might otherwise result from increased position limits for the ETF options.

FINRA understands that the ETF creation and redemption process seeks to keep an ETF's share price trading in line with the ETF's underlying net asset value. Because an ETF trades like a stock, its share price will fluctuate during the trading day, due to simple supply and demand. If demand to buy an ETF is high, for instance, the ETF's share price might rise above the value of its underlying securities. When this happens, the Authorized Participant believes the ETF may now be overpriced, so it may buy shares of the component securities and then sell ETF shares in the open market (*i.e.,* creations). This may drive the ETF's share price back toward the underlying net asset value. Likewise, if the ETF share price starts trading at a discount to the securities it holds, the Authorized Participant can buy shares of the ETF and redeem them for the underlying securities (*i.e.,* redemptions). Buying undervalued ETF shares may drive the share price of the ETF back toward fair value. This arbitrage process helps to keep an ETF's share price in line with the value of its underlying portfolio.

Surveillance and Reporting

FINRA believes that the increased position limits provisions are appropriate in light of the existing surveillance procedures and reporting requirements at FINRA,[18] the options exchanges, and at the several clearing firms, which are capable of properly identifying unusual or illegal trading activity. These procedures use daily monitoring of market movements by automated surveillance techniques to identify unusual activity in both options and underlying stocks.[19]

In addition, large stock holdings must be disclosed to the Commission by way of Schedules 13D or 13G.[20] Options positions are part of any reportable positions and cannot legally be hidden. Moreover, the previously noted Rule 2360(b)(5) requirement that members must file reports with FINRA for any customer that held aggregate large long or short positions of any single class for the previous day will continue to serve as an important part of FINRA's surveillance efforts.

Finally, FINRA believes that the current financial requirements imposed by FINRA and by the Commission adequately address financial responsibility concerns that a member or its customer will maintain an inordinately large unhedged position in any option with a higher position limit. Current margin and risk-based haircut methodologies serve to limit the size of positions maintained by any one account by increasing the margin or capital that a member must maintain for a large position. Under Rule 4210(f)(8)(A), FINRA also may impose a higher margin requirement upon a member when FINRA determines a higher requirement is warranted. In addition, the Commission's net capital rule[21] imposes a capital charge on members to the extent of any margin deficiency resulting from the higher margin requirement.

FINRA has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so FINRA can implement the proposed rule change immediately.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[22] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change promotes consistent regulation by harmonizing position limits with those of the other self-regulatory organizations. FINRA further believes that increasing the position limit on conventional options promotes consistent regulation by harmonizing the position limit with its standardized counterpart. In addition, FINRA believes the proposed rule change will be beneficial to large market makers and institutions (which generally have the greatest ability to provide liquidity and depth in products

[17] *See* iShares iBoxx $ High Yield Corporate Bond ETF, available at *https://www.ishares.com/us/products/239565/ishares-iboxx-high-yield-corporatebond-etf* (January 15, 2020).

[18] *See* Rule 2360(b)(5) for the options reporting requirements.

[19] These procedures have been effective for the surveillance of options trading and will continue to be employed.

[20] 17 CFR 240.13d–1.

[21] 17 CFR 240.15c3–1.

[22] 15 U.S.C. 78*o*–3(b)(6).

that may be subject to higher position limits as has been the case with recently approved increased position limits),[23] as well as retail traders and public customers, by providing them with a more effective trading and hedging vehicle.

In addition, FINRA believes that the structure of the Underlying ETFs, the considerable market capitalization of the funds, underlying component securities, and the liquidity of the markets for the applicable options and underlying component securities will mitigate concerns regarding potential manipulation of the products or disruption of the underlying markets upon increasing the relevant position limits. As a general principle, increases in market capitalizations, active trading volume, and deep liquidity of securities tend to deter manipulation or disruption. This general principle applies to the recently observed increased levels of market capitalization, trading volume, and liquidity in shares of the Underlying ETFs, and the components of the Underlying ETFs (as described above). FINRA does not believe that the options markets or underlying markets would become susceptible to manipulation or disruption as a result of the proposed position limit increases.

Increased position limits for select actively traded options, such as those proposed herein, are not novel and have been previously approved by the Commission. For example, a position limit of 1,800,000 contracts on options on SPY has been established.[24] Additionally, the Commission has approved similar proposed rule changes by the options exchanges to increase position and exercise limits for options on highly liquid, actively traded ETFs.[25] Furthermore, the proposed position limits on EFA and FXI are consistent with existing position limits for options on IWM and EEM, and the proposed limits for options on XLF and HYG are consistent with current position limits for options on EWZ, TLT and EWJ.

FINRA's existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior that might arise from changing position and exercise limits.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA 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.

Economic Impact Analysis

FINRA has undertaken an economic impact assessment, as set forth below, to analyze the potential economic impacts, including anticipated costs, benefits, and distributional and competitive effects transfers of wealth, relative to the current baseline, and the alternatives FINRA considered in assessing how to best meet its regulatory objectives.

Regulatory Objective

FINRA is proposing to amend Rule 2360 to harmonize FINRA's position limits for conventional options with the position limit for standardized options.[26]

Economic Baseline

Per FINRA Rule 2360(b)(3)(A)(iii) conventional equity options are subject to a basic position limit of 25,000 contracts or higher for conventional option contracts on securities that underlie exchange-traded options qualifying for a higher tier as determined by option exchange rules. The existing position limits for conventional options on ETFs are: 1,800,000 contracts for SPY, 500,000 contracts for EFA or FXI and 250,000 contracts for HYG or XLF. Cboe has recently increased position limit options on these ETFs.

Economic Impact

Benefits

As noted above, the proposed rule change would amend Rule 2360 to harmonize FINRA's position limits for conventional options with the position limits for standardized options.[27] If the existing position limits for conventional equity options on select ETFs constrains trading in these ETFs, then investors may be able to better manage risk and trade on information when the position limit is relaxed. In general, the improvement in risk management and informational efficiency may increase more when position limits are increased. FINRA acknowledges, however, that the conventional options on these ETFs, the ETFs themselves, and the securities underlying these ETFs are liquid, so improvements in informational efficiency may be relatively small.

For investors that trade conventional equity options, there is likely to be a natural size for an executed order that minimizes fixed and variable transaction costs, including but not limited to, the bid-ask spread, price impact, and transaction fees. If the existing position limits for conventional equity options on select ETFs constrains the order size such that fixed and variable transaction costs are higher than optimal, then investors may benefit if the new position limit is no less than the natural size. In such an event, the cost to hedge an ETF would decline, thereby making it less costly to manage downside risk.

In addition, if the existing position limits serve as a constraint, then an increase in the position limits for conventional options on select ETFs could permit investors to more easily find a counterparty. If the number of counterparties increases, then the cost of hedging should decline as the half-spread narrows, thereby making it less expensive to manage downside risk.

The extent of the constraint imposed by the current limit on conventional options is related to the ability of an investor to achieve similar economic exposure through other means. If there are other securities, such as an option on a closely related index, that exist and provide similar economic exposure less expensively, then the value of lessening the position limits on conventional options on ETFs is lower.

[23] *See* note 8.

[24] *See* Securities Exchange Act Release No. 83349 (May 30, 2018), 83 FR 26123 (June 5, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–MIAX–2018–11). *See also* Securities Exchange Act Release No. 83412 (June 12, 2018), 83 FR 28298 (June 18, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–PHLX–2018–44); Securities Exchange Act Release No. 83414 (June 12, 2018), 83 FR 28296 (June 18, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–BOX–2018–22); Securities Exchange Act Release No. 83415 (June 12, 2018), 83 FR 28274 (June 18, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–CBOE–2018–042); Securities Exchange Act Release No. 83413 (June 12, 2018), 83 FR 28277 (June 18, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–NYSEArca–2018–44) and Securities Exchange Act Release No. 83417 (June 12, 2018), 83 FR 28279 (June 18, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–NYSEAMER–2018–26).

[25] *See* note 6. *See also* Securities Exchange Act Release No. 68086 (October 23, 2012), 77 FR 65600 (October 29, 2012) (Order Approving File No. SR–CBOE–2012–66); Securities Exchange Act Release No. 68478 (December 19, 2012), 77 FR 76132 (December 26, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR–BOX–2012–23); Securities Exchange Act Release No. 68398 (December 11, 2012), 77 FR 74700 (December 17, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR–ISE–2012–93); Securities Exchange Act Release No. 68293 (November 27, 2012), 77 FR 71644 (December 3, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR–Phlx–2012–132); Securities Exchange Act Release No. 68358 (December 5, 2012), 77 FR 73708 (December 11, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR–NYSE MKT–2012–71); Securities Exchange Act Release No. 68359 (December 5, 2012), 77 FR 73716 (December 11, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR–NYSEArca–2012–132) and Securities Exchange Act Release No. 69457 (April 25, 2013), 78 FR 25502 (May 1, 2013) (Notice of Filing and Immediate Effectiveness of File No. SR–MIAX–2013–17).

[26] *See* note 8.

[27] *See* note 8.

Members may rely on information and data feeds from the Options Clearing Corporation to assist in their monitoring position limits. Because position limits on the standardized and conventional side have traditionally been consistent, members have relied on this feed for both standardized and conventional options. If the position limits between standardized and conventional options are conformed, then the cost from monitoring position limits should decline for member firms. Having the same position limits on standardized and conventional options, reduces the potential for excess loss that may be incurred when different limits are applied to the standardized versus conventional options on the same ETF. The economic loss may arise from building and maintaining trading and compliance systems to support the different regimes. Furthermore, the harmonization of position limits on standardized and conventional options eliminates the potential risk and cost arising from regulatory arbitrage.

Costs

The proposed rule change may impose limited operational cost on member firms that trade conventional options on ETFs, as these same firms would need to revise position limits that are used in trading systems. However, the proposed rule change should not impose additional costs, because it is difficult to disrupt or manipulate the underlying market, create an incentive to disrupt or manipulate the underlying market for the purpose of profiting from the options position, or disrupt or manipulate the options market for conventional options on ETFs affected by this proposed rule. ETFs that underlie options subject to the proposed rule change are highly liquid and are based on a broad set of highly liquid securities, which makes the market difficult to manipulate or disrupt. In fact, options on certain broad-based security indexes have no position limits. Furthermore, the creation and redemption process for these ETFs reduces the potential for disruptive or manipulative activity. New ETF units may be created at any time during the trading day and are not subject to position limits. Consequently, there is a direct link between the underlying components of the ETF and the ETF, which keeps the ETF's share prices trading in line with the ETF's underlying net asset value.

Alternatives

No further alternatives are under consideration.

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 if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act [28] and Rule 19b–4(f)(6) [29] thereunder.

FINRA has asked the Commission to waive the 30-day operative delay so that FINRA may immediately harmonize position limits with those of other self-regulatory organizations to ensure consistent regulation. For this reason, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[30]

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–FINRA–2020–021 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–FINRA–2020–021. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. 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–FINRA–2020–021, and should be submitted on or before August 19, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

J. Matthew DeLesDernier,

Assistant Secretary.

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[28] 15 U.S.C. 78s(b)(3)(A).

[29] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and the text of 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. FINRA has satisfied this requirement.

[30] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[31] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89382; File No. SR–NYSECHX–2020–22]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.37 To Add the Data Source for MEMX

July 23, 2020.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 14, 2020, the NYSE Chicago, Inc. (''NYSE Chicago'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.37 to update the Exchange's source of data feeds from MEMX LLC (''MEMX'') for purposes of order handling, order execution, order routing, and regulatory compliance. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

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 update and amend the use of data feeds table in Rule 7.37, which sets forth on a market-by-market basis the specific securities information processor (''SIP'') and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks related to each of those functions. Specifically, the Exchange proposes to amend the table in Rule 7.37(d) to specify that, with respect to MEMX, the Exchange will receive the SIP feed as its primary source of data for order handling, order execution, order routing, and regulatory compliance. The Exchange will not have a secondary source for data from MEMX.

The Exchange proposes that this proposed rule change would be operative on the day that MEMX launches operations as an equities exchange, which is currently expected on September 4, 2020.[4]

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Section 6(b)(5),[6] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes its proposal to amend the table in Rule 7.37(d) to update the data feed source for MEMX will ensure that Rule 7.37 correctly identifies and publicly states on a market-by-market basis all of the specific SIP and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks for each of those functions. The proposed rule change also removes impediments to and perfects the mechanism of a free and open market and protects investors and the public interest by providing additional specificity, clarity, and transparency in the Exchange's rules.

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 proposed change is not designed to address any competitive issue, but rather would provide the public and market participants with up-to-date information about the data feeds the Exchange will use for the handling, execution, and routing of orders, as well as for regulatory compliance.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[7] and Rule 19b–4(f)(6) thereunder.[8] Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; or (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

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)[9] of the Act to determine whether the proposed rule change should be approved or disapproved.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See https://memx.com/memx-timeline-update-launch-set-for-september-4th/.*

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(3)(A)(iii).

[8] 17 CFR 240.19b–4(f)(6).

[9] 15 U.S.C. 78s(b)(2)(B).

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–NYSECHX–2020–22 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSECHX–2020–22. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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–NYSECHX–2020–22 and should be submitted on or before August 19, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–16376 Filed 7–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89386; File No. SR–NASDAQ–2020–039]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Listing Rule IM–5900–4 To Waive the All-Inclusive Annual Listing Fee for Any Company Not Listed on a National Securities Exchange That Is Listing Upon Closing of Its Acquisition of a Special Purpose Acquisition Company Listed on Another National Securities Exchange

July 23, 2020.

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 July 9, 2020, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Listing Rule IM–5900–4 to waive the All-Inclusive Annual Listing Fee for any company not listed on a national securities exchange that is listing upon closing of its acquisition of a special purpose acquisition company listed on another national securities exchange.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq proposes to amend Listing Rule IM–5900–4 to waive the All-Inclusive Annual Listing Fee for any company not listed on a national securities exchange that is listing upon closing of its acquisition of a special purpose acquisition company (''Acquisition Company'') listed on another national securities exchange.

When an Acquisition Company consummates its business combination, it may choose a new listing venue for its post-business combination existence as an operating company. In most such cases, the Acquisition Company is the legal acquirer in the business combination transaction and thus the company transferring its listing to Nasdaq is the same entity as was listed on the other national securities exchange prior to the acquisition (*i.e.,* the Acquisition Company). When an Acquisition Company that is the legal acquirer transfers its listing to Nasdaq following the business combination, the first All-Inclusive Annual Listing Fee is waived. Specifically, Listing Rule IM–5900–4 provides that ''Nasdaq has determined to waive for the year of transfer the All-Inclusive Annual Listing Fee applicable to the year such transfer is made in the case of securities that . . . are listed on a national securities exchange but not listed on Nasdaq, if the issuer of such securities transfers their listing exclusively to Nasdaq.''

However, in fulfilling the requirements for an Acquisition Company to complete an acquisition under applicable exchange rules, occasionally the Acquisition Company is not the legal acquirer in the business combination and, instead, the business combination is structured so that the Acquisition Company is acquired by the operating company. Under the current

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Nasdaq rules, a company listing in connection with its acquisition of an Acquisition Company listed on another national securities exchange would not benefit from a similar waiver of listing fees.

To address this disparity, Nasdaq proposes to amend the fee waiver provisions of Listing Rule IM–5900–4. Specifically, the Exchange proposes to extend to any company that is not listed immediately prior to listing its class of primary equity securities upon closing of its acquisition of an Acquisition Company listed on another national securities exchange the benefits similar to those provided by Listing Rule IM–5900–4 that waives for companies transferring their securities from another exchange the requirement to pay the All-Inclusive Annual Listing Fee with respect to that class of primary equity securities or any other securities transferred in conjunction therewith for the remainder of the calendar year in which the transfer occurs. The decision whether to structure a business combination with the Acquisition Company as the legal acquirer rather than the other party does not result in the listing of a substantively different entity. Accordingly, the Exchange believes there is no basis for charging fees purely on the basis of the structure of the business combination chosen by the parties. The Exchange does not expect there to be a significant number of listings in which this proposed fee waiver will be applicable. Consequently, the proposed rule change would not affect the Exchange's commitment of resources to its regulatory oversight of the listing process or its regulatory programs.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[3] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[4] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As a preliminary matter, Nasdaq competes for listings with other national securities exchanges and companies can easily choose to list on, or transfer to, those alternative venues. As a result, the fees Nasdaq can charge listed companies are constrained by the fees charged by its competitors and Nasdaq cannot charge prices in a manner that would be unreasonable, inequitable, or unfairly discriminatory.

The Exchange believes that the proposed fee waivers are equitable as it being implemented to avoid an anomalous fee outcome arising from the manner in which an Acquisition Company business combination has been structured.

The Exchange believes that the proposal is not unfairly discriminatory, because the proposed waivers are intended to avoid the impact on a small group of issuers of an anomalous fee outcome arising from the manner in which an Acquisition Company business combination has been structured. Nasdaq also notes that such waiver is not intended to provide these issuers with any benefit that would place them in a more favorable position than other newly-listed companies, including specifically other previously unlisted companies that list upon completion of an acquisition of a company listed on Nasdaq.[5] An Acquisition Company is a shell company with no business operations. Consequently, the parties to a business combination between an Acquisition Company and an operating company have significant flexibility in how they choose to structure the business combination, including in determining which entity will be the legal acquirer.

Accordingly, the Exchange is proposing to amend its fee structure to reflect the incidental nature of the resulting Acquisition Company business combination and to avoid treating companies undergoing similar business combinations disparately.

By contrast to an Acquisition Company business combination, there are typically more significant limitations on the ability of the parties to a merger between two operating companies to make decisions about which entity will be the acquirer, including, for example, the desire to maintain the acquirer's SEC registration and concerns about how to present the combined entity to the market. As such, it is much more likely that the listing fee implications of how the transaction is structured would be a major consideration for the parties to an Acquisition Company business combination than would be the case in a merger between two operating companies. As the implications of the proposed fee waivers for decisions relating to the transaction structures utilized by unlisted companies listing in connection with the acquisition of an Acquisition Company are typically greater than for other companies listing in conjunction with merger transactions, the proposed waivers are not unfairly discriminatory.

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

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The proposed waiver will be available to all similarly situated issuers on the same basis. The Exchange does not believe that the proposed waivers will have any meaningful effect on the competition among issuers listed on the Exchange.

The Exchange operates in a highly competitive market in which issuers can readily choose to list new securities on other exchanges and transfer listings to other exchanges if they deem fee levels at those other venues to be more favorable. Because competitors are free to modify their own fees in response, and because issuers may change their listing venue, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act[6] and Rule 19b–4(f)(2)[7] 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.

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(4) and (5).

[5] Listing Rule IM–5900–1 provides for certain credits that benefit a non-Nasdaq company that lists in connection with its acquisition of a Nasdaq listed company.

[6] 15 U.S.C. 78s(b)(3)(A)(ii).

[7] 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–NASDAQ–2020–039 on the subject line.*

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2020–039. 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 submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2020–039 and should be submitted on or before August 19, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–16372 Filed 7–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89387; File No. SR–NYSEARCA–2020–67]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.37–E To Add the Data Source for MEMX

July 23, 2020.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 14, 2020, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.37–E to update the Exchange's source of data feeds from MEMX LLC (''MEMX'') for purposes of order handling, order execution, order routing, and regulatory compliance. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

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 update and amend the use of data feeds table in Rule 7.37–E, which sets forth on a market-by-market basis the specific securities information processor (''SIP'') and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks related to each of those functions. Specifically, the Exchange proposes to amend the table in Rule 7.37–E(d) to specify that, with respect to MEMX, the Exchange will receive the SIP feed as its primary source of data for order handling, order execution, order routing, and regulatory compliance. The Exchange will not have a secondary source for data from MEMX.

The Exchange proposes that this proposed rule change would be operative on the day that MEMX launches operations as an equities exchange, which is currently expected on September 4, 2020.[4]

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Section 6(b)(5),[6] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes its proposal to amend the table in Rule 7.37–E(d) to update the data feed source for MEMX will ensure that Rule 7.37–E correctly identifies and publicly states on a market-by-market basis all of the specific securities information processor and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks for each of those functions. The proposed rule change also removes

[8] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See https://memx.com/memx-timeline-update-launch-set-for-september-4th/.*

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

impediments to and perfects the mechanism of a free and open market and protects investors and the public interest by providing additional specificity, clarity, and transparency in the Exchange's rules.

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 proposed change is not designed to address any competitive issue, but rather would provide the public and market participants with up-to-date information about the data feeds the Exchange will use for the handling, execution, and routing of orders, as well as for regulatory compliance.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[7] and Rule 19b–4(f)(6) thereunder.[8] Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; or (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

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)[9] 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–2020–67 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–2020–67. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2020–67, and should be submitted on or before August 19, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–16373 Filed 7–28–20; 8:45 am]

BILLING CODE 8011–01–P

[7] 15 U.S.C. 78s(b)(3)(A)(iii).

[8] 17 CFR 240.19b–4(f)(6).

[9] 15 U.S.C. 78s(b)(2)(B).

[10] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2020–0033]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes extensions and revisions of OMB-approved information collections, as well as two new collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB) Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov*

(SSA) Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov*

Or you may submit your comments online through *www.regulations.gov,* referencing Docket ID Number [SSA–2020–0033].

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than September 28, 2020. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Online Request for Correction of Earnings Record—0960–NEW. We are offering an alternative to the paper process of requesting a correction to an

earnings record, and launching a new service that enables our users to make these same requests electronically via the online *my* Social Security portal. Information collected from the public will not exceed that which is requested by paper Form SSA–7008, OMB No. 0960–0029, Request for Correction of Earnings Record. The information we collect includes that which supports an earnings correction action, such as employer names, addresses, wage amounts, and pertinent details about the nature of employment. The respondents are authorized, authenticated individuals accessing the earnings correction process from their personal *my* Social Security portal.

Type of Request: Request for a new information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Online Request for Correction of Earnings Record	76,047	1	15	19,012	* $25.72	** $488,989

* We based this figure on average U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_stru.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

2. Statement of Death by Funeral Director—20 CFR 404.715 and 404.720—0960–0142. When an SSA-insured worker dies, the funeral director or funeral home responsible for the worker's burial or cremation completes Form SSA–721 and sends it to SSA. SSA uses this information for three purposes: (1) To establish proof of death for the insured worker; (2) to determine if the insured individual was receiving any pre-death benefits SSA needs to terminate; and (3) to ascertain which surviving family member is eligible for the lump-sum death payment or for other death benefits. The respondents are funeral directors who handled death arrangements for the insured individuals.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSA–721	544,233	1	4	36,282	* 28.06	** $1,018,073

* We based this figure on average funeral arranger's hourly salary, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes394031.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

3. Government Pension Questionnaire—20 CFR 404.408a—0960–0160. The basic Social Security benefits application (OMB No. 0960–0618) contains a lead question asking if applicants are qualified (or will qualify) to receive a government pension. If the respondent is qualified, or will qualify, to receive a government pension, the applicant completes Form SSA–3885 either on paper or through a personal interview with an SSA claims representative. If applicants are not entitled to receive a government pension at the time they apply for Social Security benefits, SSA requires them to provide the government pension information as beneficiaries when they become eligible to receive their pensions. Regardless of the timing, at some point the applicants or beneficiaries must complete and sign Form SSA–3885 to report information about their government pensions before the pensions begin. SSA uses the information to: (1) Determine whether the Government Pension Offset provision applies; (2) identify exceptions as stated in 20 CFR 404.408a; and (3) determine the benefit reduction amount and effective date. If the applicants and beneficiaries do not respond using this questionnaire, SSA offsets their entire benefit amount. The respondents are applicants or recipients of spousal benefits who are eligible for or already receiving a Government pension.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
SSA–3885	6,495	1	13	1,407	* $25.72	** 24	*** $103,009

* We based this figure on average U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_stru.htm*).

** We based this figure on the average FY 2020 wait times for field offices, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

4. Application for Benefits under a U.S. International Social Security Agreement—20 CFR 404.1925—0960–0448. Section 233(a) of the Social Security Act (Act) authorizes the President to enter into international Social Security agreements (Totalization Agreements) between the United States and foreign countries. SSA collects information using Form SSA–2490–BK to determine entitlement to Social Security benefits from the United States, or from a country that enters into a Totalization Agreement with the United States. The respondents are individuals applying for Old Age Survivors and Disability Insurance (OASDI) benefits from the United States, or from a Totalization Agreement country.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
SSA–2490–BK (MCS) ..	16,195	1	30	8,098	* $10.73	** 24	*** $156,401
SSA–2490–BK (Paper)	2,120	1	30	1,060	* 10.73	** 24	*** 20,473
Totals	18,315	.....	.....	9,158	.....	.....	*** 176,874

* We based this figure on average DI payments, as reported in SSA's disability insurance payment data (*https://www.ssa.gov/legislation/2020Fact%20Sheet.pdf*).

** We based this figure on the average FY 2020 wait times for field offices, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

5. Employee Identification Statement—20 CFR 404.702—0960–0473. When two or more individuals report earnings under the same Social Security Number (SSN), SSA collects information on Form SSA–4156 to credit the earnings to the correct individual and SSN. We send SSA–4156 to the employer to: (1) Identify the employees involved; (2) resolve the discrepancy; and (3) credit the earnings to the correct SSN. The respondents are employers involved in erroneous wage reporting for an employee.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
SSA–4156	3,600	1	10	600	* $25.72	** 24	*** $52,469

* We based this figure on average U.S. worker's hourly wages as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_stru.htm*).

** We based this figure on the average FY 2020 wait times for field offices, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

6. Public Information Campaign—0960–0544. Periodically, SSA sends various public information materials, including public service announcements, news releases, and educational tapes to public broadcasting systems so they can inform the public about various programs and activities SSA conducts. SSA frequently sends follow-up business reply cards for these public information materials to obtain suggestions for improving them. The respondents are broadcast sources.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Radio Announcement	5,000	2	1	167	* $25.76	** $4,302

* We based this figure on average Broadcast Announcers and Radio Disc Jockey's hourly salary, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes273011.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

7. SSI Notice of Interim Assistance Reimbursement (IAR)—0960–0546. Section 1631(g) of the Act authorizes SSA to reimburse an IAR agency from an individual's retroactive Supplemental Security Income (SSI) payment for assistance the IAR agency gave the individual for meeting basic needs while an SSI claim was pending or SSI payments were suspended or terminated. The State or local agency needs an IAR agreement with SSA to participate in the IAR program. The individual receiving the IAR payment signs an authorization form with an IAR agency to allow SSA to repay the IAR agency for funds paid in advance prior to SSA's determination on the

individual's claim. The authorization represents the individual's intent to file for SSI, if the individual did not file an application before SSA received the authorization. Agencies who wish to enter into an IAR agreement with SSA need to meet the following requirements:

• Reporting Requirements—Each IAR agency agrees to:

(a) Notify SSA of receipt of an authorization for initial claims or cases the agency is appealing;

(b) submit a copy of that authorization either through a manual or electronic process;

(c) inform SSA of the amount of reimbursement;

(d) submit a written request for dispute resolution on a determination;

(e) notify SSA of interim assistance paid (using the SSA–8125 or the SSA–L8125–F6);

(f) inform SSA of any deceased claimants who participate in the IAR program;

(g) review and sign an agreement with SSA.

• Recordkeeping Requirements (h & i)—the IAR agencies agree to retain all notices, agreement, authorizations, and accounting forms for the period defined in the IAR agreement so SSA may verify transactions covered under the agreement.

• Third Party Disclosure Requirements (j)—each participating IAR agency agrees to send written notices from the IAR agency to the recipient regarding payment amounts and appeal rights.

• Periodic Review of Agency Accounting Process (k–m)—the IAR agency makes the IAR accounting records of paid cases available for SSA review and verification. SSA conducts reviews either onsite or through the mail of the authorization forms, notices to the claimant and accounting forms. Upon completion of the review, SSA provides a written report of findings to the IAR agency director.

The respondents are State IAR officers.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents (States)	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden hours (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Reporting Requirements							
(a) State notification of receipt of authorization (Electronic Process)	11	6,973	76,703	1	1,278	* $19.58	** $25,023
(b) State submission of copy of authorization (Manual Process)	27	1,894	51,138	3	2,557	* 19.58	** 50,066
(c) State submission of amount of IA paid to recipients (using eIAR)	38	1,346	51,148	8	6,820	* 19.58	** 133,536
(d) State request for determination—dispute resolution	(1)	1	2	30	1	* 19.58	** 20
(e) State computation of reimbursement due form SSA using paper Form SSA–L8125–F6	38	1	38	30	4	* 19.58	** 78
(f) State notification to SSA of deceased claimant	20	2	40	15	10	* 19.58	** 196
(g) State reviewing/signing of IAR Agreement	38	1	38	[2] 12	456	* 19.58	** 8,928
Recordkeeping Requirements							
(h) Maintenance of authorization forms	38	3,364	[3] 127,832	3	6,392	* 21.09	** 134,807
(i) Maintenance of accounting forms and notices	38	1,346	51,148	3	2,557	* 21.09	** 53,927
Third Party Disclosure Requirements							
(j) Written notice from State to recipient regarding amount of payment	38	2668	101,384	7	11,828	* 19.58	** 231,592
Periodic Review of Agency Accounting Process							
(k) Retrieve and consolidate authorization and accounting forms	12	1	12	3	36	* 21.09	** 759

Modality of completion	Number of respondents (States)	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden hours (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
(l) Participate in periodic review	12	1	12	16	192	* 21.09	** 4,049
(m) Correct administrative and accounting discrepancies	6	1	6	4	24	* 21.09	** 506
Total Administrative Burden							
Total	38		408,353		32,155		** 643,487

[1] Average of about 2 States per year.
[2] Hours.
[3] Includes both denied and approved SSI claims.
* We based this figure on average Social and Human Services Assistants (*https://www.bls.gov/oes/current/oes211093.htm*), and Information and Records Clerks (*https://www.bls.gov/oes/current/oes434199.htm*).
** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

8. Appeal of Determination for Extra Help with Medicare Prescription Drug Plan Costs—0960–0695. Public Law 108–173, the Medicare Perscription Drug, Improvement, and Modernization Act of 2003, established the Medicare Part D program for voluntary prescription drug coverage for certain low-income individuals. The law provides for subsidies for individuals who are eligible for the program and who meet eligibility criteria for help with premium, deductible, and co-payment costs. SSA uses Form SSA–1021, Appeal of Determination for Extra Help With Medicare Prescription Drug Plan Costs, to obtain information from individuals who appeal SSA's decisions regarding eligibility or continuing eligibility for a Medicare Part D subsidy. The respondents are Medicare beneficiaries, or representative payee applicants acting on behalf of a Medicare beneficiary, who do not agree with the outcome of an SSA subsidy eligibility determination, and are filing an appeal.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
SSA–1021 (Paper version)	2,872	1	10	479	* $25.72	0	*** $12,320
SSA–1021 (Intranet version: MAPS)	9,691	1	10	1,615	* 25.72	** 24	*** 141,229
Totals	12,563			2,094			*** 153,549

* We based this figure on average U.S. worker's hourly wages as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_stru.htm*).
** We based this figure on the average FY 2020 wait times for field offices, based on SSA's current management information data.
*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

9. Request for Medical Treatment in an SSA Employee Health Facility: Patient Self-Administered or Staff Administered Care—0960–0772. SSA operates onsite Employee Health Clinics (EHC) in eight different States. These clinics provide health care for all SSA employees including treatments of personal medical conditions when authorized through a physician. Form SSA–5072 is the employee's personal physician's order form. The information we collect on Form SSA–5072 gives the EHC nurses the guidance they need to perform certain medical procedures and to administer prescription medications such as allergy immunotherapy. In addition, the information allows the SSA medical officer to determine whether the nurses can administer treatment safely and appropriately in the SSA EHCs. Respondents are physicians of SSA employees who need to have medical treatment in an SSA EHC.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSA–5072 Annually	25	1	25	5	2	* $96.85	** $194
SSA–5072 Bi-Annually	75	2	150	5	13	* 96.85	** 1,259

Modality of completion	Number of respondents	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Totals	100				15		** 1,453

* We based this figure on average physician's hourly salary, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes291216.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

10. Medicare Income-Related Monthly Adjustment Amount—Life-Changing Event Form—0960–0784. Federally mandated reductions in the Federal Medicare Part B and prescription drug coverage subsidies result in selected Medicare recipients paying higher premiums due to income above a specific threshold. The amount of the premium subsidy reduction is an income-related monthly adjustment amount (IRMAA). The Internal Revenue Service (IRS) transmits income tax return data to SSA for SSA to determine the IRMAA. SSA uses the Form SSA–44 to determine if a recipient qualifies for a reduction in the IRMAA. If affected Medicare recipients believe SSA should use more recent tax data because of a life-changing event that significantly reduces their income, they can report these changes to SSA and ask for a new initial determination of their IRMAA. The respondents are Medicare Part B and prescription drug coverage Retirement Insurance recipients and enrollees with modified adjusted gross income over a high-income threshold who experience one of eight significant life-changing event.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
Personal Interview (SSA field office)	178,840	1	30	89,420	* $25.72	** 24	*** $4,139,788
SSA–44	76,645	1	45	57,484	* 25.72	0	*** 1,478,488
Totals	255,485			146,904			*** 5,618,276

* We based this figure on average U.S. worker's hourly wages as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_stru.htm*).

** We based this figure on the average FY 2020 wait times for field offices, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

11. Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery—0960–0788. SSA, as part of our continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on the ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery '' for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.). We developed this collection as part of a Federal Government-wide effort to streamline the process for seeking feedback from the public on service delivery.

Under the auspices of Executive Order 12862, Setting Customer Service Standards, SSA conducts multiple satisfaction surveys each year. This proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with SSA's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between SSA and our customers and stakeholders.

The solicitation of feedback will target areas such as: Timeliness; appropriateness; accuracy of information; courtesy; efficiency of service delivery; and resolution of issues with service delivery. We will assess responses to plan and inform efforts to improve or maintain the quality of service offered to the public. If we do not collect this information, we would not have access to vital feedback from customers and stakeholders on SSA's services.

We will only submit a collection for approval under this generic clearance if it meets the following conditions: (1) The collections are voluntary; (2) the collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government; (3) the collections are non-controversial and do not raise issues of concern to other Federal agencies; (4) any collection targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future; (5) we collect personally identifiable information (PII) only to the extent necessary and we do not retain it; (6) we will use information gathered only internally for general service improvement and program management

purposes and we will not release it outside of the agency; (7) we will not use information we gather for the purpose of substantially informing influential policy decisions; and (8) information we gather will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

The respondents are recipients of SSA services (including most members of the public), professionals, and individuals who work on behalf of SSA beneficiaries.

Type of Request: Extension of an OMB-approved information collection.

Affected Public: Individuals and households, businesses and organizations, State, Local or Tribal government.

Total Estimated Number of Respondents: 5,454,212.

Below we provide projected average estimates for the next three years:

Annual Respondents: 1,818,404.

Annual Responses: 1,818,404.

Frequency of Response: Once per request.

Average Minutes per Response: 13 minutes (12.6912).

Estimated Annual Burden: 384,629 hours.

II. SSA submitted the information collection below to OMB for clearance. Your comments regarding this information collection would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than August 28, 2020. Individuals can obtain copies of the OMB clearance package by writing to *OR.Reports.Clearance@ssa.gov.*

1. Notice to Electronic Information Exchange Partners to Provide Contractor List—0960–NEW. The Privacy Act of 1974, E-Government Act of 2002, and the National Institute of Standard Special Publications 800–53–4 require the SSA to maintain oversight of the information it provides to Electronic Information Exchange Partners (EIEPs). EIEPs obtain SSA data for the administration of federally funded and state-administered programs. SSA has a responsibility to monitor and protect the personally identifiable information SSA shares with other Federal and State agencies, and private organizations through the Computer Matching and Privacy Protection Act, and the Information Exchange Agreements (IEA). Under the terms of the State Transmission Component IEA, and agency IEA, EIEPs agree to comply with Electronic Information Exchange security requirements and procedures for State and local agencies exchanging electronic information with SSA. SSA's Technical Systems Security Requirements document provides that all agencies using SSA data ensure that SSA information is not processed, maintained, transmitted, or stored in (including by means of data communications channel) any electronic devices, computers, or computer networks located in geographic or virtual areas not subject to U.S. law. SSA conducts tri-annual compliance reviews of all State and local agencies, and Tribes with whom we have an IEA, to verify appropriate security safeguards remain in place to protect the confidentiality of information SSA supplies. SSA requires any organization with an electronic data exchange agreement, to provide the SSA Regional Office contact a current list of contractors, or agents who have access to SSA data upon request. SSA uses Form SSA–731, Notice to Electronic Information Exchange Partners to Provide Contractor List, to collect this information. The respondents are Federal agencies; State, local, or tribal agencies; who exchange electronic information with SSA.

Type of Request: Request for a new information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSA–731	300	1	20	100	* $18.00	** $3,960

* We based this figure on average State, local and tribal government worker's salaries (*https://www.bls.gov/oes/current/oes434199.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

2. Application for Survivor's Benefits—20 CFR 404.611(a) and (c)—0960–0062. Surviving family members of armed services personnel can file for Social Security and veterans' benefits with SSA or at the Veterans Administration (VA). Applicants filing for Title II survivor benefits at the VA complete Form SSA–24, which the VA forwards to SSA for processing. SSA uses the information to determine eligibility for benefits. The respondents are survivors of deceased armed services personnel who are applying for benefits at the VA.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
SSA–8060–U3	3,200	1	15	800	* $25.72	** 24	*** $53,498

* We based this figure on average U.S. worker's hourly wages as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_stru.htm*).
** We based this figure on the average FY 2020 wait times for field offices, based on SSA's current management information data.
*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

3. Railroad Employment Questionnaire—20 CFR 404.1401, 404.1406–404.1408—0960–0078. Railroad workers, their dependents, or survivors can concurrently apply for railroad retirement and Social Security benefits at SSA if the number holder, or claimant on the number holder's Social Security Number, worked in the railroad industry. SSA uses Form SSA–671 to coordinate Social Security claims processing with the Railroad Retirement Board and to determine benefit entitlement and amount. The respondents are Social Security benefit applicants previously employed by a railroad or dependents of railroad workers.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
SSA–671	125,000	1	5	10,417	* $25.72	** 24	*** $1,553,925

* We based this figure on average U.S. worker's hourly wages as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_stru.htm*).
** We based this figure on the average FY 2020 wait times for field offices, based on SSA's current management information data.
*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

4. Modified Benefit Formula Questionnaire-Employer—20 CFR 404.213 and 404.243—0960–0477. Sections 215(a)(7) and 215(d)(3) of the Social Security Act requires SSA to use a modified benefit formula to compute Social Security retirement or disability benefits for persons first eligible (after 1985) for both a Social Security benefit and a pension or annuity, based on employment not covered by Social Security. This method is the Windfall Elimination Provision (WEP). SSA makes a determination regarding whether the WEP applies, and when to apply it to a person's benefit. SSA uses Form SSA–58 to verify the claimant's allegations on Form SSA–150 (OMB No. 0906–0395, Modified Benefits Formula Questionnaire). SSA also uses Form SSA–58 to determine if the modified benefit formula applies, and when to apply it to a person's benefits. SSA sends Form SSA–58 to an employer for pension related information, if the claimant is unable to provide it. The respondents are employers of people who are eligible after 1985 for both Social Security benefits and a pension based on work not covered by SSA.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSA–58	26,925	1	3	1,346	* $20.39	** $27,445

* We based this figure on average Information and Records Clerks (*https://www.bls.gov/oes/current/oes434199.htm*).
** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

5. myWageReport—20 CFR 404.1520(b), 404.1571–404.1576, & 404.1584–404.1593—0960–0808. The myWageReport application will enable Social Security Disability Insurance (SSDI) beneficiaries, and representative payees to report earnings electronically. It will also generate a receipt for the beneficiary or representative payee, providing confirmation that SSA has received the earnings report. SSA will screen the information submitted through the myWageReport application and will determine if we need additional employment information. If so, agency personnel will reach out to beneficiaries, or their representative payees and will use Form SSA–821, Work Activity Report (0960–0059), to collect the additional required information. The respondents for this collection are SSDI recipients or their representative payees.

Type of Request: Revision of an OMB approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
myWageReporting	88,000	1	7	10,267	* $10.73	** $110,165

* We based this figure on average DI payments, as reported in SSA's disability insurance payment data (*https://www.ssa.gov/legislation/2020Fact%20Sheet.pdf*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

Date: July 23, 2020.

Naomi Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2020–16361 Filed 7–28–20; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Opportunity for Public Comment To Change the Land Use From Aeronautical to Non Aeronautical for 31.2 Acres at Old Town Municipal Airport, Old Town, ME

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Request for Public Comments.

SUMMARY: Notice is being given that the FAA is considering a request from the Town of Old Town, ME to change the land use from Aeronautical to Non Aeronautical for 31.2 acres of airport land. The land use change will allow the development of a solar farm on land that is not needed for aeronautical purposes. The revenue generated by the lease of airport land for the solar farm will be placed into the airport's operation and maintenance fund.

DATES: Comments must be received on or before August 25, 2020.

ADDRESSES: You may send comments using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov,* and follow the instructions on providing comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W 12–140, 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.

Interested persons may inspect the request and supporting documents by contacting the FAA at the address listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Mr. Jorge E. Panteli, Compliance and Land Use Specialist, Federal Aviation Administration New England Region Airports Division, 1200 District Avenue, Burlington, Massachusetts 01803. Telephone: 781–238–7618.

Issued in Burlington, Massachusetts on July 24, 2020.

Julie Seltsam-Wilps,

Deputy Director, ANE–600.

[FR Doc. 2020–16430 Filed 7–28–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 2020–0387]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Domestic and International Flight Plans

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves extracting flight data such as aircraft, routing speed, etc. from domestic and international flights. FAA Form 7233–1, Flight Plan: Domestic flight plan information is used to govern the flight of aircraft for the protection and identification of aircraft and property and persons on the ground. The information is used by air traffic controllers, search and rescue (SAR) personnel, flight standards inspectors, accident investigators, military, law enforcement, and the Department of Homeland Security. FAA Form 7233–4, International Flight Plan: International flight plan information is used for the same purposes as domestic flight plans; in addition, it is used by Customs and international controllers.

DATES: Written comments should be submitted by August 28, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Aldwin Humphrey by email at: *aldwin.humphrey@faa.gov;* phone: 703–786–9859.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0026.

Title: Domestic and International Flight plans.

Form Numbers: FAA form7233–1 Domestic Flight Plan, FAA form 7233–4 International Flight Plan.

Type of Review: Renewal of information collection.

Background: The Federal Aviation Administration (FAA) is authorized and directed by Title 49, United States Code, paragraph 40103(b), to prescribe air traffic rules and regulations governing the flight of aircraft for the protection and identification of aircraft and property and persons on the ground. Title 14, CFR, Part 91, Subchapter F, prescribes flight rules governing the operation of aircraft within the United States. These rules govern the operation of aircraft (other than moored balloons, kites, unmanned rockets and unmanned free balloons) within the United States and for flights across international

borders. Paragraphs 91.153 and 91.169, address flight plan information requirements. Paragraph 91.173 states requirements for when an instrument flight rules (IFR) flight plan must be filed. International Standards Rules of the Air, Annex 2 to the Convention on International Civil Aviation paragraph 3.3 states requirements for filing international flight plans. In addition, a Washington, District of Columbia (DC) Special Flight Rules Area (SFRA) was implemented requiring pilots operating within a certain radius of Washington, DC to follow special security flight rules. The SFRA also includes three (3) general aviation airports in Maryland (College Park, Clinton/Washington Executive/Hyde Field, and Friendly/Potomac Airfield) where pilots are required to file a flight plan regardless of whether they are flying under visual flight rules (VFR) or IFR. This collection of information supports the Department of Homeland Security and the Department of Defense in addition to the normal flight plan purposes.

Almost 100 percent of flight plans are filed electronically. However, as a courtesy to the aviation public, flight plans may be submitted in paper form. Flight plans may be filed in the following ways:

- Air carrier and air taxi operations, and certain corporate aviation departments, have been granted authority to electronically file flight plans directly with the FAA. The majority of air carrier and air taxi flights are processed in this manner.
- Air carrier and air taxi operators may submit pre-stored flight plan information on scheduled flights to Air Route Traffic Control Centers (ARTCC) to be entered electronically at the appropriate times.
- Pilots may call 1–800–WX–BRIEF (992–7433) and file flight plans with a flight service station specialist who enters the information directly into a computer system that automatically transmits the information to the appropriate air traffic facility. Pilots calling certain flight service stations have the option of using a voice recorder to store the information that will later be entered by a specialist.
- Private and corporate pilots who fly the same aircraft and routes at regular times may prestore flight plans with flight service stations. The flight plans will then be entered automatically into the air traffic system at the appropriate time.
- Pilots who visit a flight service station in person may choose to a file flight plan by using a paper form. The data will then be entered into a computer and filed electronically. The pilot will often keep the paper copy for his/her record.

Respondents: Air carrier and air taxi operations, and certain corporate aviation departments, General Aviation Pilots.

Frequency: On occasion.

Estimated Average Burden per Response: 2.5 minutes per flight plan.

Estimated Total Annual Burden: 718,618 hours.

Issued in Washington, DC, on July 23, 2020.

Aldwin E. Humphrey,

Air Traffic Control Specialist, Office of Flight Service Safety and Operations, AJR–B.

[FR Doc. 2020–16377 Filed 7–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Office of Commercial Space Transportation: Notice of Availability of the Final Environmental Assessment and Finding of No Significant Impact for SpaceX Falcon Launches at Kennedy Space Center and Cape Canaveral Air Force Station

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), Council on Environmental Quality NEPA implementing regulations, and FAA Order 1050.1F, *Environmental Impacts: Policies and Procedures,* the FAA is announcing the availability of the Final Environmental Assessment and Finding of No Significant Impact for SpaceX Falcon Launches at Kennedy Space Center and Cape Canaveral Air Force Station (Final EA and FONSI).

FOR FURTHER INFORMATION CONTACT: Daniel Czelusniak, Environmental Protection Specialist, Federal Aviation Administration, 800 Independence Avenue SW, Suite 325, Washington, DC 20591; phone (202) 267–5924; email *Daniel.Czelusniak@faa.gov.*

SUPPLEMENTARY INFORMATION: SpaceX is applying to the FAA for launch licenses to launch the Falcon 9 and Falcon Heavy from Kennedy Space Center's (KSC) Launch Complex 39A (LC–39A) and Cape Canaveral Air Force Station's (CCAFS) Launch Complex 40 (LC–40). SpaceX is also applying to the FAA for reentry licenses for Dragon reentry operations. The FAA's proposal to issue licenses to SpaceX is considered a major federal action subject to environmental review under NEPA. Due to SpaceX's ability to launch more frequently at KSC and CCAFS, SpaceX's launch manifest includes more annual Falcon launches and Dragon reentries than were considered in previous NEPA analyses. Also, SpaceX is proposing to add a new Falcon 9 southern launch trajectory from Florida for payloads requiring polar orbits. SpaceX is also proposing to construct a mobile service tower (MST) at LC–39A to support commercial launches and the U.S. Air Force's National Security Space Launch program. NASA is responsible for approving the construction of the MST at LC–39A. The FAA has no federal action related to the construction of the MST.

The Final EA evaluated the potential environmental impacts of the Proposed Action and the No Action Alternative. Under the No Action Alternative, the FAA would not modify existing SpaceX licenses or issue new licenses to SpaceX for Falcon launches or Dragon reentry operations at KSC and CCAFS. SpaceX would continue Falcon 9 and Falcon Heavy launch operations at KSC and CCAFS, as well as Dragon reentry operations, as analyzed in previous NEPA and environmental reviews and in accordance with existing FAA licenses until the licenses expire.

The FAA published a Draft EA for public comment on February 27, 2020. The FAA received six public comment submissions. The FAA has posted the Final EA and FONSI on the FAA Office of Commercial Space Transportation website: *https://www.faa.gov/space/environmental/nepa_docs/.*

Issued in Washington, DC on: July 10, 2020.

Daniel Murray,

Manager, Safety Authorization Division.

[FR Doc. 2020–16428 Filed 7–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No.: PHMSA–2019–0098]

Hazardous Materials: Lithium Battery Air Safety Advisory Committee; Notice of Public Meeting; Correction

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), U.S. Department of Transportation (DOT).

ACTION: Notice of public meeting; correction.

SUMMARY: PHMSA published a document in the **Federal Register** of March 30, 2020, announcing a meeting

of the Lithium Battery Air Safety Advisory Committee. The document indicated that the meeting would be held at DOT Headquarters in Washington, DC, but it will now be hosted virtually with no in-person meeting being conducted.

FOR FURTHER INFORMATION CONTACT: Steven Webb or Aaron Wiener, PHMSA, U.S. Department of Transportation. Telephone: (202)–366–8553. Email: *lithiumbatteryFACA@dot.gov.* Any committee related request should be sent to the person listed in this section.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of March 30, 2020, in FR Doc. 2020–06492, on page 17615, in the first column, correct the **ADDRESSES** caption to read:

ADDRESSES: The meeting will be hosted virtually and will be open to the public. The meeting will also be recorded and archived. Information for accessing the virtual meeting will be posted on the Committee website. The Lithium Battery Air Safety Advisory Committee website is located at: *https://www.phmsa.dot.gov/hazmat/rulemakings/lithium-battery-safety-advisory-committee.* The E-Gov website is located at *https://www.regulations.gov.* Mailed written comments intended for the Committee should be sent to Docket Management Facility; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590–0001. Hand delivered written comments should be delivered to the DOT dockets facility located in Room W12–140 on the ground level of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

William Quade,

Deputy Associate Administrator Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2020–16368 Filed 7–28–20; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treas.gov/ofac*).

Notice of OFAC Actions

On July 13, 2020, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

Individuals:

1. LAVRENKOV, Igor Valerievich (Cyrillic: ЛАВРЕНКОВ, Игорь Валерьевич), Surat Thani 84320, Thailand; Chaoyang District, Beijing, China; DOB 30 Jan 1974; POB Russia; nationality Saint Kitts and Nevis; alt. nationality Russia; Gender Male; Passport RE0028598 (Saint Kitts and Nevis); alt. Passport RE0013455 (Saint Kitts and Nevis); alt. Passport 51NO5354610 (Russia) (individual) [UKRAINE-EO13661] [CYBER2] [ELECTION-EO13848] (Linked To: PRIGOZHIN, Yevgeniy Viktorovich).

   Designated pursuant to section 2(a)(ii) of Executive Order 13848 of September 12, 2018, "Imposing Certain Sanctions in the Event of Foreign Interference in a United States Election," 83 FR 46843, 3 CFR, 2019 Comp., p. 869 (E.O. 13848), for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13848.

   Also designated pursuant to section 1(a)(iii)(B) of Executive Order 13694 of April 1, 2015, "Blocking Property of Certain Persons Engaging in Significant Malicious Cyber-Enabled Activities," 80 FR 18077, 3 CFR 2016 Comp., p. 297, as amended by Executive Order 13757 of December 28, 2016, "Taking Additional Steps to Address the National Emergency With Respect to Significant Malicious Cyber-Enabled Activities," 82 FR 1, 3 CFR 2017 Comp., p. 659, (E.O. 13694, as amended) for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13694, as amended.

   Also designated pursuant to section 1(a)(ii)(D)(2) of Executive Order 13661 of March 16, 2014, "Blocking Property of Additional Persons Contributing to the Situation in Ukraine," 79 FR 15535, 3 CFR 2015 Comp., p. 229, (E.O. 13661) for having

materially assisted sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13661.

2. MANDEL, Andrei Sergeevich (Cyrillic: МАНДЕЛЬ, Андрей Сергеевич), St. Petersburg, Russia; DOB 02 Mar 1990; POB Germany; Gender Male; Passport 753615660 (individual) [UKRAINE-EO13661] [CYBER2] [ELECTION-EO13848] (Linked To: M INVEST, OOO).

   Designated pursuant to section 2(a)(iii) of E.O. 13848 for having acted or purported to act for or on behalf of, directly or indirectly, M INVEST, OOO, an entity whose property and interests in property are blocked pursuant to E.O. 13848.

   Also designated pursuant to section 1(a)(iii)(C) of E.O. 13694, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, M INVEST, OOO, an entity whose property and interests in property are blocked pursuant to E.O. 13694, as amended.

   Also designated pursuant to section 1(a)(ii)(C)(2) of E.O. 13661 for having acted or purported to act for or on behalf of, directly or indirectly, M INVEST, OOO, an entity whose property and interests in property are blocked pursuant to E.O. 13661.

3. POTEPKIN, Mikhail Sergeyevich, Sudan; DOB 29 Sep 1981; alt. DOB 19 Sep 1981; nationality Russia; Gender Male; Passport 651697952 (Russia) (individual) [UKRAINE-EO13661] [CYBER2] [ELECTION-EO13848] (Linked To: M INVEST, OOO; Linked To: MEROE GOLD CO. LTD.).

   Designated pursuant to section 2(a)(iii) of E.O. 13848 for having acted or purported to act for or on behalf of, directly or indirectly, M INVEST, OOO, an entity whose property and interests in property are blocked pursuant to E.O. 13848.

   Also designated pursuant to section 2(a)(iii) of E.O. 13848 for having acted or purported to act for or on behalf of, directly or indirectly, MEROE GOLD CO. LTD., an entity whose property and interests in property are blocked pursuant to E.O. 13848.

   Also designated pursuant to section 1(a)(iii)(C) of E.O. 13694, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, M INVEST, OOO, an entity whose property and interests in property are blocked pursuant to E.O. 13694, as amended.

   Also designated pursuant to section 1(a)(iii)(C) of E.O. 13694, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, MEROE GOLD CO. LTD., an entity whose property and interests in property are blocked pursuant to E.O. 13694, as amended.

Also designated pursuant to section 1(a)(ii)(C)(2) of E.O. 13661 for having acted or purported to act for or on behalf of, directly or indirectly, M INVEST, OOO, an entity whose property and interests in property are blocked pursuant to E.O. 13661.

Also designated pursuant to section 1(a)(ii)(C)(2) of E.O. 13661 for having acted or purported to act for or on behalf of, directly or indirectly, MEROE GOLD CO. LTD., an entity whose property and interests in property are blocked pursuant to E.O. 13661.

Entities:

1. SHEN YANG JING CHENG MACHINERY IMP&EXP. CO., LIMITED (Chinese Traditional: 安營集團有限公司) (a.k.a. SHEN YANG JING CHENG MACHINERY IMPANDEXP. CO., LIMITED), Tsim Sha Tsui, Hong Kong; Surat Thani 84320, Thailand; Beijing, China; Wan Chai, Hong Kong; Causeway Bay, Hong Kong; Central, Hong Kong; Identification Number 1328682 (Hong Kong) [UKRAINE-EO13661] [CYBER2] [ELECTION-EO13848] (Linked To: PRIGOZHIN, Yevgeniy Viktorovich).

   Designated pursuant to section 2(a)(ii) of E.O. 13848 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13848.

   Also designated pursuant to section 1(a)(iii)(B) of E.O. 13694, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13694, as amended.

   Also designated pursuant to section 1(a)(ii)(D)(2) of E.O. 13661 for having materially assisted sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13661.

2. SHINE DRAGON GROUP LIMITED (Chinese Traditional: 尚龍集團有限公司), Central, Hong Kong; Surat Thani 84320, Thailand; Tsim Sha Tsui, Kowloon, Hong Kong; Causeway Bay, Hong Kong; Identification Number 1329358 (Hong Kong) [UKRAINE-EO13661] [CYBER2] [ELECTION-EO13848] (Linked To: PRIGOZHIN, Yevgeniy Viktorovich).

   Designated pursuant to section 2(a)(ii) of E.O. 13848 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13848.

Also designated pursuant to section 1(a)(iii)(B) of E.O. 13694, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13694, as amended.

Also designated pursuant to section 1(a)(ii)(D)(2) of E.O. 13661 for having materially assisted sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13661.

3. ZHE JIANG JIAYI SMALL COMMODITIES TRADE COMPANY LIMITED, Mong Kok, Hong Kong; Surat Thani 84320, Thailand; Jiaxing, Zhejiang Province, China; Tsim Sha Tsui, Kowloon, Hong Kong; Central, Hong Kong; Identification Number 1328910 (Hong Kong) [UKRAINE-EO13661] [CYBER2] [ELECTION-EO13848] (Linked To: PRIGOZHIN, Yevgeniy Viktorovich).

   Designated pursuant to section 2(a)(ii) of E.O. 13848 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13848.

   Also designated pursuant to section 1(a)(iii)(B) of E.O. 13694, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13694, as amended.

   Also designated pursuant to section 1(a)(ii)(D)(2) of E.O. 13661 for having materially assisted sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13661.

4. M INVEST, OOO (Cyrillic: ООО М ИНВЕСТ), d. 76 korp. 4 litera A ofis N620, prospekt Obukhovskoi Oborony, St. Petersburg, Russia; Khartoum, Sudan; Tax ID No. 7811636632 (Russia); Government Gazette Number 06513574 (Russia); Registration Number 1177847044066 (Russia) [UKRAINE-EO13661] [CYBER2] [ELECTION-EO13848] (Linked To: PRIGOZHIN, Yevgeniy Viktorovich).

   Designated pursuant to section 2(a)(iii) of E.O. 13848 for being owned or controlled by YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13848.

Also designated pursuant to section 1(a)(iii)(C) of E.O. 13694, as amended, for being owned or controlled by YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13694, as amended.

Also designated pursuant to 1(a)(ii)(C)(2) of E.O. 13661 for being owned or controlled by YEVGENIY VIKTOROVICH PRIGOZHIN, a person whose property and interests in property are blocked pursuant to E.O. 13661.

5. MEROE GOLD CO. LTD., Al-jref Gharb Plot 134, Blok 1h, Khartoum, Sudan; Organization Type: Mining of other non-ferrous metal ores [UKRAINE-EO13661] [CYBER2] [ELECTION-EO13848] (Linked To: M INVEST, OOO).

Designated pursuant to section 2(a)(iii) of E.O. 13848 for being owned or controlled by M INVEST, OOO, an entity whose property and interests in property are blocked pursuant to E.O. 13848.

Also designated pursuant to section 1(a)(iii)(C) of E.O. 13694, as amended, for being owned or controlled by M INVEST, OOO, an entity whose property and interests in property are blocked pursuant to E.O. 13694, as amended.

Also designated pursuant to 1(a)(ii)(C)(2) of E.O. 13661 for being owned or controlled by M INVEST, OOO, an entity whose property and interests in property are blocked pursuant to E.O. 13661.

Dated: July 13, 2020.

Andrea M. Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2020–15680 Filed 7–28–20; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Forms 943, 943–PR, 943–A, and 943A–PR and 943 (Schedule R)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 943, Employer's Annual Tax Return for Agricultural Employees, 943–PR, Planilla Para La Declarcion Annual De La Contribucion Federal Del Patrono De Empleados Agricolas, 943–A, Agricultural Employer's Record of Federal Tax Liability, and 943A–PR, Registro De La Obligacion Contributiva Del Patrono Agricola, and 943 (Schedule R), Allocation Schedule for Aggregate Form 943 Filers.

DATES: Written comments should be received on or before September 28, 2020 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Forms 943,Employer's Annual Tax Return for Agricultural Employees, 943–PR, Planilla Para La Declarcion Annual De La Contribucion Federal Del Patrono De Empleados Agricolas, 943–A, Agricultural Employer's Record of Federal Tax Liability, and 943A–PR, Registro De La Obligacion Contributiva Del Patrono Agricola, and 943 (Schedule R), Allocation Schedule for Aggregate Form 943 Filers.

OMB Number: 1545–0035.

Form Number: 943, 943–PR, 943–A, 943A–PR, and 943 (Schedule R).

Abstract: Agricultural employers must prepare and file Form 943 and Form 943–PR (Puerto Rico only) to report and pay FICA taxes and income tax voluntarily withheld (Form 943 only). Agricultural employees may attach Forms 943–A and 943A–PR to Forms 943 and 943–PR to show their tax liabilities for semiweekly periods. The information is used to verify that the correct tax has been paid. Form 943 (Schedule R) allows (1) an agent appointed by an employer or payer or (2) a customer who enters into a contract that meets the requirements under 7705(e)(2) or (3) a client who enters into a service agreement described under Regulations section 31.3504–2(b)(2) with a Certified Professional Employer Organization, to allocate information reported on Form 943 to each client.

Current Actions: Changes were made according to Section 7001 of Public Law 116–127—Payroll credit for required paid sick leave, Section 7003 of Public Law 116–127 Payroll credit for required family leave, Section 2301 of Public Law 116–136 Employee retention credit, and Section 2302 of Public Law 116–136 Delay of payment of employer payroll taxes.

New lines were added to report qualified sick leave wages and qualified family leave wages, to calculate the employee share of social security tax on qualified sick and family leave wages, and to report the nonrefundable portion of the credit for qualified sick and family leave wages and retention credit. The instructions will have a worksheet to figure these amounts. Additional lines are added to report total nonrefundable credits, to report the deferred payment of the employer share of social security tax, to report the refundable portion of the credit for qualified sick and family leave wages and refundable portion of the employee retention credit. Editorial changes and lines to report the totals, and request additional information related to the new credits were also added.

Schedule R (Form 943) has been revised to accommodate all of the new lines added to the 2020 Form 943.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for profit organizations.

Estimated Number of Respondents: 965,698.

Estimated Time per Respondent: 12r., 53 min.

Estimated Total Annual Burden Hours: 12,440,285.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 23, 2020,

Martha Brinson,

Tax Analyst.

[FR Doc. 2020–16449 Filed 7–28–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0567]

Agency Information Collection Activity: (Presidential Memorial Certificate Form)

AGENCY: National Cemetery Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the National Cemetery Administration (NCA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–0567.

SUPPLEMENTARY INFORMATION:

Authority: Public Law 104–13; 44 U.S.C. 3501–21.

Title: Presidential Memorial Certificate Form VA form 40–0247.

OMB Control Number: 2900–0567.

Type of Review: Revision of a currently approved collection.

Abstract: The Presidential Memorial Certificate (PMC) is an engraved paper certificate, signed by a current U.S. President, to honor the memory of deceased Veterans who are eligible for burial in a national cemetery. VA Form 40–0247 information collection is required to properly inscribe and address for delivery of the PMC. Supporting military or discharge documents are also needed to verify that the veteran's character of service and duty status meet program eligibility and legal requirements. NCA is updating Form VA 40–0247 to include personal information necessary for statistical data gathering, targeted outreach and utilization trend analysis.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at Volume, 85, No. 97 on Tuesday, May 19, 2020, page 30023.

Affected Public: Individuals or Households.

Estimated Annual Burden: 6,250 hours.

Estimated Average Burden per Respondent: 3 minutes.

Frequency of Response: One-time.

Estimated Number of Respondents: 125,000.

By direction of the Secretary.

Danny S. Green,

Department Clearance Officer, Office of Quality, Performance and Risk, Department of Veterans Affairs.

[FR Doc. 2020–16384 Filed 7–28–20; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Advisory Committee on Rehabilitation, Amended Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that the Veterans' Advisory Committee on Rehabilitation (VACOR) will meet virtually on Wednesday, August 19 and Thursday, August 20, 2020 from 10:00 a.m. to 3:00 p.m. EST both days. The virtual meeting sessions is open to the public.

The purpose of the Committee is to advise the Secretary of VA on the rehabilitation needs of Veterans with disabilities and on the administration of VA's rehabilitation programs.

On August 19, 2020, Committee members will welcome members and provide briefings from the Central Texas Veterans Health Care System on various tele-health services designed to enhance the rehabilitation potential of Veterans, particularly Veterans in rural areas.

On August 20, 2020, Committee members will receive briefings from the Waco Regional Office on various virtual services designed to enhance the

rehabilitation potential of Veterans. Committee members will discuss recommendations to be included in the Committee's next annual comprehensive report.

Time will be allocated for receiving oral comments from the public. Members of the public may submit written comments for review by the Committee to Latrese Arnold, Designated Federal Officer, Veterans Benefits Administration (28), 810 Vermont Avenue NW, Washington, DC 20420, or at *Latrese.Arnold@va.gov.* In the communication, writers must identify themselves and state the organization, association or person(s) they represent. For any members of the public that wish to attend virtually, they may use the WebEx link: *https://veteransaffairs.webex.com/veteransaffairs/e.php?MTID=m32739e83c249b52c53f3b7036a1ad0a0,* password: VACOR*Aug20, or join by phone at 1–404–397–1596,1997448005#.

Dated: July 24, 2020.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2020–16386 Filed 7–28–20; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0546]

Agency Information Collection Activity Under OMB Review: Gravesite Reservation Questionnaire

AGENCY: National Cemetery Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the National Cemetery Administration (NCA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–0546.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–3521.

Title: Gravesite Reservation Questionnaire.

OMB Control Number: 2900–0546.

Type of Review: Extension of a currently approved collection.

Abstract: The information is needed to determine if individuals holding gravesite set-asides wish to retain their set-aside or their wish to relinquish it. 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.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at Vol. 85, No. 103/Thursday, May 28, 2020, pages 32102.

Affected Public: Individuals or Households.

Estimated Annual Burden: 4,166 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 25,000.

By direction of the Secretary.

Danny S. Green,

Department Clearance Officer, Office of Quality, Performance and Risk, Department of Veterans Affairs.

[FR Doc. 2020–16431 Filed 7–28–20; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 85 Wednesday,
No. 146 July 29, 2020

Part II

The President

Federal Register
Vol. 85, No. 146
Wednesday, July 29, 2020

Presidential Documents

Title 3—

The President

Proclamation 10058 of July 24, 2020

Anniversary of the Americans With Disabilities Act, 2020

By the President of the United States of America

A Proclamation

On the 30th anniversary of the Americans with Disabilities Act (ADA), we celebrate the landmark legislation that helped opened the door for every person with a disability to participate fully and independently in our society. Today, we reflect on the progress we have made as a Nation in securing equal rights and defending the inherent dignity of all Americans, and we reaffirm our commitment to further advancing accessibility for those with disabilities.

Since the ADA became law three decades ago, it has facilitated greater opportunities for Americans with disabilities to engage in their communities, improving access to employment, government services, public accommodations, commercial facilities, and public transportation. Building on this foundation, my Administration is supporting the full participation and inclusion of the more than 61 million Americans currently living with disabilities by continuing to work to expand their access to everyday life. We have established an unprecedented level of coordination across the Federal Government in addressing the significant gaps in employment between Americans with and without disabilities through our Multi-Agency Task Force on Improving Employment for People with Disabilities. We also continue to encourage research that will advance technology and medicine to allow Americans with disabilities to live more independent lives. Additionally, in order to help ease the financial burdens that Americans with disabilities often face, we are raising awareness of Achieving a Better Life Experience (ABLE) accounts, which allow money to be saved for qualified disability-related expenses without having to pay taxes on earnings.

As our Nation continues to battle the coronavirus, my Administration has remained committed to the principles of the ADA, working to ensure that no American is denied the care they need because of a disability. We have removed barriers and invested in communities and States to help those with disabilities safely stay home if they become ill. In April, the Department of Health and Human Services announced nearly $1 billion in grants to help meet the needs of older Americans and persons with disabilities during the crisis. This funding is providing in-home care to those who need it and direct support and services to those who are experiencing disruptions to their independent, community-based living due to the pandemic. It is also helping to connect people at greatest risk of serious illness from the coronavirus, as well as to services needed to practice social distancing and to mitigate issues such as social isolation.

Through their tenacity and grit, Americans with disabilities have made contributions that have strengthened our country. As we reopen workplaces, we will once again implement an economic agenda that delivers unprecedented opportunities to people with disabilities. Already, Federal agencies are working together to help people who acquire disabilities due to illness, including the coronavirus, or injury return to their jobs and support their families. My Administration's Retaining Employment and Talent after Injury/Illness Network (RETAIN) demonstration project, managed by the Department of Labor and the Social Security Administration, is testing new ways to

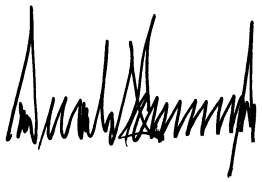
help ill or injured workers stay on the job or resume employment as soon as medically possible so they can keep supporting their families and contributing to the economy.

At the same time, my Administration's historic investment in apprenticeship is paving new career pathways, and we are committed to ensuring that they are accessible to all, including youth and adults with disabilities. The Apprenticeship Inclusion Models (AIM) demonstration project at the Department of Labor is piloting approaches to open up new pathways to high-demand careers in industries such as technology and healthcare.

On this milestone anniversary of the ADA, we recommit to the full inclusion of all persons with disabilities in America. Together, we will continue to remove the barriers that prevent Americans with disabilities from harnessing their full potential.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim July 26, 2020, as a day in celebration of the 30th Anniversary of the Americans with Disabilities Act. I call upon all Americans to observe this day with appropriate ceremonies and activities that celebrate the contributions of Americans with disabilities and to renew our commitment to achieving the promise of our freedom for all Americans.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-fourth day of July, in the year of our Lord two thousand twenty, and of the Independence of the United States of America the two hundred and forty-fifth.



[FR Doc. 2020–16591
Filed 7–28–20; 11:15 am]
Billing code 3295–F0–P

Presidential Documents

Proclamation 10059 of July 24, 2020

National Korean War Veterans Armistice Day, 2020

By the President of the United States of America

A Proclamation

Sixty-seven years ago today, guns fell silent along the Korean Demilitarized Zone after more than 3 years of brutal fighting to defeat the expansion of communism on the Korean Peninsula. On National Korean War Veterans Armistice Day, we pause to remember the uncommon courage and sacrifice of ordinary Americans who fought to defend freedom and protect the values we hold dear.

This year marks the 70th anniversary of the start of the Korean War. When the conflict began, Americans were still rebuilding their lives in the aftermath of World War II, enjoying the blessings of peace and looking toward a future filled with hope and prosperity. When freedom and democracy were under threat on the Korean Peninsula, however, 2 million Americans left their homes, put on our Nation's uniform, and answered their country's call to duty. Their resolve was tried and tested in once obscure and unfamiliar places, such as Pork Chop Hill, Heartbreak Ridge, Chipyong-ni, Pusan, and the Chosin Reservoir, and in unnamed locations known only by grid coordinates or hilltop elevations. Alongside tens of thousands of coalition troops from our allies around the world, these individuals fought, bled, died, went missing, and suffered brutal captivity to defeat a determined foe amid the harshest of conditions, including sweltering heat, bone-numbing cold, and deep snow that buried valleys and rugged ridgelines. Their unquestioned valor, determination, and patriotism halted communist aggression and restored liberty and dignity for the South Korean people. In our Nation's Capital, the black granite wall of the Korean War Veterans Memorial stands as a testament to their sacrifice, etched with the words ''Freedom is Not Free.'' In total, more than 36,000 Americans gave their lives in the Korean War, more than 103,000 were wounded, and nearly 8,000 went missing in action.

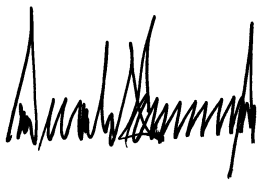
Today, the Republic of Korea, once decimated in the aftermath of the war, is one of the world's most vibrant, dynamic, and economically prosperous democracies—and one of our strongest allies. Our Armed Forces continue to proudly serve side-by-side with our Korean military counterparts. This ironclad alliance, forged in war and reinforced by a shared love of liberty and deep ties of friendship, is vital to peace and stability in both Asia and the world.

As we commemorate the 67th anniversary of the Korean War Armistice, we renew our commitment to the principles of liberty for which our Korean War veterans so valiantly fought. We are eternally grateful for the families that endured the unimaginable sacrifices and heartache of war, and we are thankful for all the men and women who helped change the fate of a nation. The 38 months of bloody warfare represent the honorable legacy of a selfless and courageous generation of American patriots.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim July 27, 2020, as National Korean War Veterans Armistice Day. I call upon all Americans

to observe this day with appropriate ceremonies and activities that honor and give thanks to our distinguished Korean War Veterans.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-fourth day of July, in the year of our Lord two thousand twenty, and of the Independence of the United States of America the two hundred and forty-fifth.



[FR Doc. 2020–16593
Filed 7–28–20; 11:15 am]
Billing code 3295–F0–P

FEDERAL REGISTER

Vol. 85 Wednesday,
No. 146 July 29, 2020

Part III

The President

Federal Register
Vol. 85, No. 146
Wednesday, July 29, 2020

Presidential Documents

Title 3—

The President

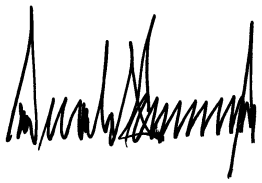
Memorandum of July 7, 2020

Delegation of Authority Under the Better Utilization of Investments Leading to Development Act of 2018

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby delegate to the Secretary of State the authority vested in the President by section 1412(c)(2)(A) of the Better Utilization of Investments Leading to Development Act of 2018 (title I of division F of Public Law 115–254) (the ''Act'') to certify to the appropriate congressional committees that the provision of support under title II of the Act in a less developed country with an upper-middle-income economy furthers the national economic or foreign policy interests of the United States. The delegation in this memorandum shall apply to any provision of any future public law that is the same or substantially the same as the provision referenced in this memorandum.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, July 7, 2020

[FR Doc. 2020–16601
Filed 7–28–20; 11:15 am]
Billing code 4710–10–P

Presidential Documents

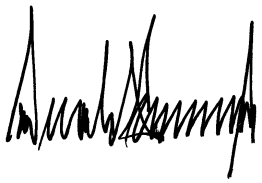
Presidential Determination No. 2020–09 of July 17, 2020

Continuation of U.S. Drug Interdiction Assistance to the Government of Colombia

Memorandum for the Secretary of State [and] the Secretary of Defense

By the authority vested in me as President by the Constitution and the laws of the United States, and pursuant to the authority vested in me by section 1012 of the National Defense Authorization Act for Fiscal Year 1995, as amended (22 U.S.C. 2291–4), I hereby certify, with respect to Colombia, that: (1) interdiction of aircraft reasonably suspected to be primarily engaged in illicit drug trafficking in that country's airspace is necessary, because of the extraordinary threat posed by illicit drug trafficking to the national security of that country; and (2) Colombia has appropriate procedures in place to protect against innocent loss of life in the air and on the ground in connection with such interdiction, which includes effective means to identify and warn an aircraft before the use of force is directed against the aircraft.

The Secretary of State is authorized and directed to publish this determination in the *Federal Register* and to notify the Congress of this determination.



THE WHITE HOUSE,
Washington, July 17, 2020

[FR Doc. 2020–16622
Filed 7–28–20; 11:15 am]
Billing code 4710–10–P

FEDERAL REGISTER

Vol. 85 Wednesday,

No. 146 July 29, 2020

Part IV

The President

Federal Register
Vol. 85, No. 146
Wednesday, July 29, 2020

Presidential Documents

Title 3—

The President

Executive Order 13937 of July 24, 2020

Access to Affordable Life-Saving Medications

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Purpose.* Insulin is a critical and life-saving medication that approximately 8 million Americans rely on to manage diabetes. Likewise, injectable epinephrine is a life-saving medication used to stop severe allergic reactions.

The price of insulin in the United States has risen dramatically over the past decade. The list price for a single vial of insulin today is often more than $250 and most patients use at least two vials per month. As for injectable epinephrine, recent increased competition is helping to drive prices down. Nevertheless, the price for some types of injectable epinephrine remains more than $600 per kit. While Americans with diabetes and severe allergic reactions may have access to affordable insulin and injectable epinephrine through commercial insurance or Federal programs such as Medicare and Medicaid, many Americans still struggle to purchase these products.

Federally Qualified Health Centers (FQHCs), as defined in section 1905(l)(2)(B)(i) and (ii) of the Social Security Act, as amended, 42 U.S.C. 1396d(l)(2)(B)(i) and (ii), receive discounted prices through the 340B Prescription Drug Program on prescription drugs. Due to the sharp increases in list prices for many insulins and some types of injectable epinephrine in recent years, many of these products may be subject to the ''penny pricing'' policy when distributed to FQHCs, meaning FQHCs may purchase the drug at a price of one penny per unit of measure. These steep discounts, however, are not always passed through to low-income Americans at the point of sale. Those with low-incomes can be exposed to high insulin and injectable epinephrine prices, as they often do not benefit from discounts negotiated by insurers or the Federal or State governments.

Sec. 2. *Policy.* It is the policy of the United States to enable Americans without access to affordable insulin and injectable epinephrine through commercial insurance or Federal programs, such as Medicare and Medicaid, to purchase these pharmaceuticals from an FQHC at a price that aligns with the cost at which the FQHC acquired the medication.

Sec. 3. *Improving the Availability of Insulin and Injectable Epinephrine for the Uninsured.* To the extent permitted by law, the Secretary of Health and Human Services shall take action to ensure future grants available under section 330(e) of the Public Health Service Act, as amended, 42 U.S.C. 254b(e), are conditioned upon FQHCs' having established practices to make insulin and injectable epinephrine available at the discounted price paid by the FQHC grantee or sub-grantee under the 340B Prescription Drug Program (plus a minimal administration fee) to individuals with low incomes, as determined by the Secretary, who:

(a) have a high cost sharing requirement for either insulin or injectable epinephrine;

(b) have a high unmet deductible; or

(c) have no health care insurance.

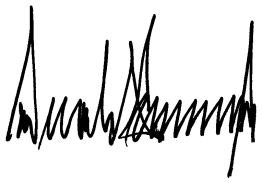
Sec. 4. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof;

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
July 24, 2020.

[FR Doc. 2020–16623
Filed 7–28–20; 2:00 pm]
Billing code 3295–F0–P

Presidential Documents

Executive Order 13938 of July 24, 2020

Increasing Drug Importation To Lower Prices for American Patients

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Purpose.* Americans spend more per capita on pharmaceutical drugs than residents of any other developed country. Americans often pay more for the exact same drugs, even when they are produced and shipped from the exact same facilities.

One way to minimize international disparities in price is to increase the trade of prescription drugs between nations with lower prices and those with persistently higher ones. Over time, reducing trade barriers and increasing the exchange of drugs will likely result in lower prices for the country that is paying more for drugs. For example, in the European Union, a market characterized by price controls and significant barriers to entry, the parallel trade of drugs has existed for decades and has been estimated to reduce the price of certain drugs by up to 20 percent. Accordingly, my Administration supports the goal of safe importation of prescription drugs.

Sec. 2. *Permitting the Importation of Safe Prescription Drugs from Other Countries.* The Secretary of Health and Human Services shall, as appropriate and consistent with applicable law, take action to expand safe access to lower-cost imported prescription drugs by:

(a) facilitating grants to individuals of waivers of the prohibition of importation of prescription drugs, provided such importation poses no additional risk to public safety and results in lower costs to American patients, pursuant to section 804(j)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 384(j)(2);

(b) authorizing the re-importation of insulin products upon a finding by the Secretary that it is required for emergency medical care pursuant to section 801(d) of the FDCA, 21 U.S.C. 381(d); and

(c) completing the rulemaking process regarding the proposed rule to implement section 804(b) through (h) of the FDCA, 21 U.S.C. 384(b) through (h), to allow importation of certain prescription drugs from Canada.

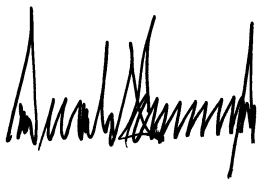
Sec. 3. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
July 24, 2020.

[FR Doc. 2020–16624
Filed 7–28–20; 2:00 pm]
Billing code 3295–F0–P

Presidential Documents

Executive Order 13939 of July 24, 2020

Lowering Prices for Patients by Eliminating Kickbacks to Middlemen

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Purpose.* One of the reasons pharmaceutical drug prices in the United States are so high is because of the complex mix of payers and negotiators that often separates the consumer from the manufacturer in the drug-purchasing process. The result is that the prices patients see at the point-of-sale do not reflect the prices that the patient's insurance companies, and middlemen hired by the insurance companies, actually pay for drugs. Instead, these middlemen—health plan sponsors and pharmacy benefit managers (PBMs)—negotiate significant discounts off of the list prices, sometimes up to 50 percent of the cost of the drug. Medicare patients, whose cost sharing is typically based on list prices, pay more than they should for drugs while the middlemen collect large ''rebate'' checks. These rebates are the functional equivalent of kickbacks, and erode savings that could otherwise go to the Medicare patients taking those drugs. Yet currently, Federal regulations create a safe harbor for such discounts and preclude treating them as kickbacks under the law.

Fixing this problem could save Medicare patients billions of dollars. The Office of the Inspector General at the Department of Health and Human Services has found that patients in the catastrophic phase of the Medicare Part D program saw their out-of-pocket costs for high-price drugs increase by 47 percent from 2010 to 2015, from $175 per month to $257 per month. Narrowing the safe harbor for these discounts under the anti-kickback statute will allow tens of billions in dollars of rebates on prescription drugs in the Medicare Part D program to go directly to patients, saving many patients hundreds or thousands of dollars per year at the pharmacy counter.

Sec. 2. *Policy.* It is the policy of the United States that discounts offered on prescription drugs should be passed on to patients.

Sec. 3. *Directing Drug Rebates to Patients Instead of Middlemen.* The Secretary of Health and Human Services shall complete the rulemaking process he commenced seeking to:

(a) exclude from safe harbor protections under the anti-kickback statute, section 1128B(b) of the Social Security Act, 42 U.S.C. 1320a–7b, certain retrospective reductions in price that are not applied at the point-of-sale or other remuneration that drug manufacturers provide to health plan sponsors, pharmacies, or PBMs in operating the Medicare Part D program; and

(b) establish new safe harbors that would permit health plan sponsors, pharmacies, and PBMs to apply discounts at the patient's point-of-sale in order to lower the patient's out-of-pocket costs, and that would permit the use of certain bona fide PBM service fees.

Sec. 4. *Protecting Low Premiums.* Prior to taking action under section 3 of this order, the Secretary of Health and Human Services shall confirm—and make public such confirmation—that the action is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs.

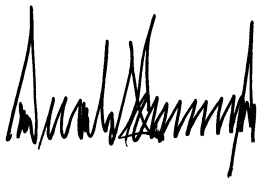
Sec. 5. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
July 24, 2020.

[FR Doc. 2020–16625
Filed 7–28–20; 2:00 pm]
Billing code 3295–F0–P

Reader Aids

Federal Register

Vol. 85, No. 146

Wednesday, July 29, 2020

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FEDERAL REGISTER PAGES AND DATE, JULY

CFR PARTS AFFECTED DURING JULY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
10053 39821
10054 40085
10055 40087
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