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Rules and Regulations

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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 315 and 330

RIN 3206–AN79

Hiring Authority for College Graduates

AGENCY: Office of Personnel Management.

ACTION: Interim rule with request for comments.

SUMMARY: The Office of Personnel Management (OPM) is issuing an interim rule, with an opportunity for comment, to amend its career and career-conditional employment regulations. The revision is necessary to implement the John S. McCain National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019, which requires OPM to issue regulations, in interim final form, establishing hiring authorities for college graduates into positions at specified grades in the competitive service. The intended effect of the authority is to provide additional flexibility in hiring eligible and qualified individuals.

DATES:

Effective date: This interim rule is effective December 6, 2021.

Comments due date: OPM must receive comments on or before January 4, 2022.

ADDRESSES: You may submit comments, identified by the docket number or Regulation Identifier Number (RIN) for this proposed rulemaking, by the following method:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for sending comments.

All submissions must include the agency name and docket number or RIN for this rulemaking. Please arrange and identify your comments on the regulatory text by subpart and section number; if your comments relate to the supplementary information, please refer to the heading and page number. All comments received will be posted without change, including any personal information provided. Please ensure your comments are submitted within the specified open comment period. Before finalizing this rule, OPM will consider all comments we receive on or before the closing date for comments. OPM may make changes to the final rule in light of the comments we receive.

FOR FURTHER INFORMATION CONTACT: Katika Floyd at (202) 606–0960, by fax at (202) 606–4430, TDD at (202) 418–3134, or by email at *employ@opm.gov*.

SUPPLEMENTARY INFORMATION: On August 13, 2018, the President signed Public Law 115–232, the National Defense Authorization Act for Fiscal Year 2019, (*i.e.,* the Act). Section 1108 of the Act established a new hiring authority, codified at 5 U.S.C. 3115, for appointing college graduates into positions at specified grades in the competitive service. This section also directs OPM to issue regulations, on an interim final basis, to implement this authority. Section 1108 of the Act also established a hiring authority for the time-limited appointments of Post-Secondary Students. OPM will issue regulations to implement the hiring authority for Post-Secondary students in a separate notice.

OPM is issuing interim regulations, with an opportunity for comments, that will create a new section 315.614 in subpart F of part 315, title 5, Code of Federal Regulations (CFR), and revise part 330 Recruitment, Selection, and Placement (General) to implement these provisions.

The interim rule for college graduates allows agencies to make appointments of eligible individuals directly into the competitive service, without regard to 5 U.S.C. 3309–3319 and 3330. Readers should note that this new hiring authority is separate and distinct from the Pathways Program and other programs for recent graduates authorized under the Executive Order 13562 (establishing the Pathways Programs, and providing for appointments in the excepted service for Interns, Recent Graduates, and Presidential Management Fellows as defined in that Order).

When using this authority, agencies must provide public notification in accordance with Section 1108, as codified at 5 U.S.C. 3315, and the merit system principles, and notify OPM, in accordance with 5 U.S.C. 3327(b). Because section 1108 of the Act waives the requirement for OPM to post a vacancy to be filled under this authority that would otherwise apply (5 U.S.C. 3330), agencies are not required to use *www.USAJOBS.gov* (*i.e.,* USAJOBS) to provide notice of these vacancies. Although posting on USAJOBS is optional, 5 U.S.C. 3327 requires agencies to notify OPM of the vacancies they intend to fill under this authority. OPM will provide additional information on meeting the requirements of 5 U.S.C. 3327(b) in supplemental guidance. Agencies may wish to use USAJOBS, nevertheless, in light of that system's ability to assist with the requirement to collect demographic information. Moreover, agencies must, pursuant to 5 U.S.C. 3327(b), notify OPM of positions to be filled through this authority, whether or not an agency uses USAJOBS. Agencies must advertise positions in a manner that provides for ''diverse and qualified applicants,'' 5 U.S.C. 3115(d)(2)(B), and ''ensure[s] that potential applicants have appropriate information relevant to the positions'' being filled. *Id.* at 3115(d)(2)(C). As indicated in 5 U.S.C. 3115(c), agencies must determine whether an applicant meets the eligibility requirements for the College Graduates hiring authority before giving that applicant further consideration. Agencies must then assess whether an eligible applicant meets the government-wide (*i.e.,* OPM-approved) or OPM-approved agency-specific minimum qualification standard for the position being filled.

Agencies are not required to provide selection priority to eligible and qualified applicants entitled to selection priority in accordance with 5 CFR part 330 subparts F, and G pertaining to Agency Career Transition Assistance Plans (CTAP), and Interagency Career Transition Assistance Plans (ICTAP). OPM has revised these subparts to include exceptions to these provisions when appointments are made using the college graduate authority.

Section 1108 of the Act also allows agencies to make appointments without regard to any provision of sections 3309 through 3319 of title 5. An agency may select any eligible individual who meets each minimum qualification standard, without regard to the application of veterans' preference, but must follow merit system principles, 5 U.S.C. 2301, in so doing. Agencies may appoint

individuals under this authority to career or career conditional appointments (as appropriate) in the competitive service at the grade levels specified in 5 U.S.C. 3115.

OPM is adding a new § 315.614,

Interim § 315.614(a) *Agency authority* establishes that an agency may noncompetitively appoint an eligible and qualified College Graduate to any position classified by OPM in the administrative or professional series at or below the General Schedule (GS) 11 level (or equivalent).

Interim § 315.614(b) *Eligibility* defines an eligible College Graduate as an individual who has received a bachelors or advanced degree within two years of submitting an application for employment under this authority. For these purposes, a baccalaureate or graduate degree must be obtained from an institution of higher education in accordance with section 101(a) of the Higher Education Act of 1965, as codified at 20 U.S.C. 1001(a). The two-year eligibility period begins on the date the degree is received, not the date of the graduation ceremony. An agency may accept applications from applicants prior to the applicant receiving a degree. If such an applicant is selected, the applicant may not be appointed until after the degree is completed. An applicant who has applied for a specific position within the two-year eligibility period may be appointed to that position after the two-year eligibility period expires. For example, if a student receives a degree in May of 2020 and applies for a position in April of 2022; then the appointment may be made after May of 2022. The date on which an application is submitted is the date on which it was received by the hiring agency.

This section also makes clear that for individuals who have completed a degree and have an intervening period of obligated service of at least four years in the uniformed services, the two-year eligibility period begins on the date of the individual's discharge or release from the uniformed service. The intervening period of uniformed service must prevent the individual from applying within the standard two-year period for applying after completing a degree. For example, a service member completes a master's degree in May 2018 while serving in a four-year enlistment period that ends in May 2021. The service member's two-year eligibility period under the authority will begin in May 2021, upon discharge or release from uniformed service, because they were unable to apply and accept a position while completing their service obligation. Or an individual in the Reserve Officers Training Corps (ROTC) who has a four-year service obligation after graduation would be eligible to apply for a position under the authority within two years of completing the four-year service obligation.

Interim § 315.614(c) *Qualifications* explains that individuals appointed under this authority must meet each OPM-prescribed minimum qualification standard, or OPM-approved agency-specific minimum qualification standard, for the position being filled.

Interim § 315.614(d) *Classification* establishes that an agency may appoint an eligible and qualified individual to any position classified in the administrative and professional series at the GS 11 level or below (or equivalent), including positions with promotion potential beyond the GS–11 level. Agencies may refer to OPM's, ''Introduction to the Position Classification Standards,'' available at *https://www.opm.gov/policy-data-oversight/classification-qualifications/classifying-general-schedule-positions/positionclassificationintro.pdf* for a definition of these positions. In addition, agencies can refer to the ''Handbook of Occupational Groups and Families'' available at *https://www.opm.gov/policy-data-oversight/classification-qualifications/classifying-general-schedule-positions/occupationalhandbook.pdf.*

Interim § 315.614(e) *Public notification* contains the public notice and advertising requirements agencies must follow before filling a position using this provision. This section explains that if an agency using this authority does not use USAJOBS to post the position it must post a job announcement on its public facing home web page (home page), or at a minimum, display a link to the job announcement on the hiring agency's public facing home page. Agencies are free to additionally post announcements directly on third party recruitment boards (*e.g.,* LinkedIn, Monster, Yello) as long as the agency's public facing homepage also includes a link to a specific announcement.

This section requires that the agency's job announcement must include the following information about the position being filled: The position's title, series, grade level (or equivalent), minimum qualifications, the position's salary, whether the position has promotion potential to a higher grade(s), any pertinent flexibilities that may be offered in conjunction with the position (*e.g.,* telework opportunities or student loan repayments), and information on how to apply. This section also requires the agency to adhere to the merit system principles and perform appropriate recruiting and advertising activities to foster a diverse and qualified applicant pool when using the authority. An agency may use USAJOBS to satisfy the public notification requirements and the requirements of 5 U.S.C. 3327. If USAJOBS is not used to advertise a position(s), the agency must satisfy the requirements of 5 U.S.C. 3327 by providing OPM link(s) to the public notification(s) used to solicit applicants as those links are posted.

Interim § 315.614(f) *Appointment Type* makes clear that individuals are appointed to permanent career or career-conditional positions in the competitive service.

Interim § 315.614(g) *Acquisition of competitive status* explains that an individual appointed under this provision acquires competitive status upon completion of a probationary period in accordance with subpart H of this part.

Interim § 315.614(h) *Tenure upon appointment* states that an individual appointed under this provision becomes a career or career-conditional employee in accordance with § 315.201.

Interim § 315.614(i) *Limitation on the number of appointments* restricts the number of appointments an agency may make using this authority in a fiscal year. This section specifies that the number of appointments in any fiscal year may not exceed fifteen percent of the number of individuals appointed by the agency the previous fiscal year (*i.e.,* the fiscal year prior to the fiscal year in which an agency is using this authority) to professional or administrative positions at the GS–11 level (or equivalent) or below under competitive examining procedures. An appointing agency may not count appointments made using direct hire authorities or excepted service authorities, or selections under merit promotion authorities, when establishing the limit for a given fiscal year. In calculating this limitation, agencies must round up or down to the nearest whole number, if necessary, to eliminate a decimal place. Values ending in ''.5'' may be rounded up to the nearest whole number in determining an agency's cap limitation. Values ending in less than ''.5'' should be rounded down to the nearest whole number in determining an agency's cap limitation. For example, 15% of 217 is 32.55, which should be rounded up to 33 or .15% of 235 is 35.25, which should be rounded down to 35. This section also provides that OPM may establish a lower percentage limitation based on any factor OPM deems appropriate. OPM shall notify agencies

via the OPM website and other venues (such as the Chief Human Capital Officer's Council) of any changes to the numerical limitation.

Interim § 315.614(j) *Reporting requirements* describes the type of data and frequency at which agencies must provide information to the Congress and OPM on their use of this authority. Agencies will be required to provide data on the total number of appointments; the grade levels and occupational series of the positions filled; the numerical limit established for the authority; the number of those appointed who have been separated; recruitment activities; and any difficulties encountered in using the authority. OPM will provide written guidance following publication of this rule describing the means by which agencies should collect this information, the timing of such collection and the groups as to which information should be collected.

Interim § 315.614(j)(2) establishes that OPM may request from agencies any additional information that it deems necessary to further evaluate the impact and effectiveness of this authority.

Interim § 315.614(k) describes the special provisions on the use of the authority by Department of Defense (DoD) in relation to other DoD specific hiring authorities.

Waiver of Proposed Rulemaking

Section 3115(f) of Title 5 of the U.S. Code, as enacted by section 1108(a) of Public Law 115–232 (Aug. 13, 2018), the John S. McCain National Defense Authorization Act for Fiscal Year (FY) 2019 (NDAA), directs the rulemaking shall be through ''interim regulations, with an opportunity to comment.'' Therefore, a general notice of proposed rulemaking, as typically required for rulemaking under 5 U.S.C. 553(b) and 1103(b) need not be issued in advance of this rule.

Expected Impact of This Interim Rule

OPM is issuing this rule to implement 5 U.S.C. 3115. This statute establishes a hiring authority for college graduates into certain positions at specified grades in the competitive service. The statute and this implementing regulation will allow agencies to make appointments of college graduates directly into the competitive service positions, without regard to rating, ranking and veterans' preference provisions in 5 U.S.C. 3309–3319 and 3330. This authority will be a useful tool as part of an overall strategy to implement strategic workforce and recruitment plans.

Costs

This interim final rule will affect the operations of over eighty Federal agencies—ranging from cabinet-level departments to small independent agencies. We estimate that this rule will require individuals employed by these agencies to develop policies and procedures to implement the rule and perform outreach and recruitment activities when using the authority. For the purpose of this cost analysis, the assumed average salary rate of Federal employees performing this work will be the rate in 2021 for GS–14, step 5, from the Washington, DC, locality pay table ($138,66 annual locality rate and $66.54 hourly locality rate). We assume that the total dollar value of labor, which includes wages, benefits, and overhead, is equal to 200 percent of the wage rate, resulting in an assumed labor cost of $133.08 per hour.

In order to comply with the regulatory changes in this interim final rule, affected agencies will need to review the rule and update their policies and procedures. We estimate that, in the first year following publication of the final rule, this will require an average of 250 hours of work by employees with an average hourly cost of $133.08. This would result in estimated costs in that first year of implementation of about $33,270 per agency, and about $2,661,600 governmentwide. We do not believe this rule will substantially increase the ongoing administrative costs to agencies, including the administrative costs of administering the program and hiring and training new staff.

Benefits

This authority will allow agencies to use strategic recruiting to hire recent college graduates to fill professional and administrative positions at the GS–11 level and below. When using the authority agencies will have additional flexibility in how college graduates are hired. Federal agencies will determine recruitment sources and processes for the solicitation of applications and will be held responsible for merit-based selections. This authority—when combined with agencies strategic recruitment plans—may help agencies better recruit to fill mission critical occupations.

Executive Order 12866

Executive Order 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). In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget as a significant, but not economically significant rule.

Regulatory Flexibility Act

The Director of the Office of Personnel Management certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Federalism

We have examined this rule in accordance with Executive Order 13132, Federalism, and have determined that this rule will not have any negative impact on the rights, roles and responsibilities of State, local, or tribal governments.

Civil Justice Reform

This regulation meets the applicable standard set forth in Executive Order 12988.

Unfunded Mandates Reform Act of 1995

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

Congressional Review Act

Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act or CRA) (5 U.S.C. 801 *et seq.*) requires rules to be submitted to Congress before taking effect. OPM will submit to Congress and the Comptroller General of the United States a report regarding the issuance of this rule before its effective date, as required by 5 U.S.C. 801. The Office of Information and Regulatory Affairs in the Office of Management and Budget has determined that this rule is not a major rule as defined by the CRA, 5 U.S.C. 804.

Paperwork Reduction Act (44 U.S.C. 3501–3521)

This rule does not impose any new reporting or record-keeping requirements subject to the Paperwork Reduction Act.

List of Subjects in 5 CFR Part 315

Government employees.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

Accordingly, OPM is amending parts 315 and 330 of title 5, Code of Federal Regulations, as follows:

PART 315—CAREER AND CAREER CONDITIONAL EMPLOYMENT

■ 1. The authority citation for part 315 is revised to read as follows:

Authority: 5 U.S.C. 1302, 3301, and 3302; E.O. 10577, 3 CFR, 1954–1958 Comp. p. 218, unless otherwise noted; and E.O. 13162. Secs. 315.601 and 315.609 also issued under 22 U.S.C. 3651 and 3652. Secs. 315.602 and 315.604 also issued under 5 U.S.C. 1104. Sec. 315.603 also issued under 5 U.S.C. 8151. Sec. 315.605 also issued under E.O. 12034, 3 CFR, 1978 Comp. p.111. Sec. 315.606 also issued under E.O. 11219, 3 CFR, 1964–1965 Comp. p. 303. Sec. 315.607 also issued under 22 U.S.C. 2560. Sec. 315.608 also issued under E.O. 12721, 3 CFR, 1990 Comp. p. 293. Sec. 315.610 also issued under 5 U.S.C. 3304(c). Sec. 315.611 also issued under 5 U.S.C. 3304(f). Sec. 315.612 also under E.O. 13473. Sec 315.613 also issued under Pub. L. 114–47, 2(a) (Aug. 7, 2015), amended by Pub. L. 114–328, 1135 (Dec. 23, 2016), as codified at 5 U.S.C. 9602. Sec. 315.614 also is issued under 5 U.S.C. 3115. Sec. 315.708 also issued under E.O. 13318, 3 CFR, 2004 Comp. p. 265. Sec. 315.710 also issued under E.O. 12596, 3 CFR, 1978 Comp. p. 264.

Subpart F—Career or Career-Conditional Appointment Under Special Authorities

■ 2. Add § 315.614 to read as follows:

§ 315.614 Hiring Authority for College Graduates.

(a) *Appointment authority.* In accordance with the provisions of this section, an agency may appoint noncompetitively an eligible and qualified individual to a position classified in a professional or administrative occupational category at the general schedule (GS) 11 level (or equivalent) or below, without regard to the provisions of 5 U.S.C. 3309 through 3319 and 3330.

(b) *Eligibility.* An eligible college graduate is defined as an individual who:

(1) Has received a baccalaureate or graduate degree from an institution of higher education as defined in 20 U.S.C. 1001(a); and

(i) Has submitted an application for the position being filled under this authority (using the date on which the application is received by the hiring agency as the date of submission).

(ii) Not later than two years after the date on which the individual received their degree described in paragraph (b)(1) introductory text of this section; or

(iii) in the case of an individual who has completed a period of not less than four years of intervening obligated service in a uniformed service, not later than two years after the date on which the individual was released or discharged from that uniformed service.

(2) Meets the minimum qualification standards prescribed or approved by OPM for the position to which the individual is being appointed.

(c) *Qualifications.* Agencies must evaluate eligible college graduates using the OPM-prescribed qualification standard, or an OPM-approved agency-specific minimum qualification standard, for the position being filled.

(d) *Classification.* An agency may make an initial appointment of an eligible and qualified individual to any position classified according to OPM classification standards in a professional or administrative occupational series at the GS–11 level (or equivalent) or below, including positions with promotion potential beyond the GS–11.

(e) *Public notice and advertising.* An agency must adhere to merit system principles, and thus must publicly advertise the position in a manner that endeavors to reach qualified individuals from all segments of society, including notifying OPM, in accordance with 5 U.S.C. 3327(b), before filling a position under this authority. To meet this requirement, an agency must display information about the position to be filled on its home page (that is accessible to the general public). An agency may, but is not required to, use *www.USAJOBS.gov* for this purpose. Alternatively, an agency may either provide an actual job announcement on its public-facing web page (home page) or provide a link to the job announcement on its public-facing homepage. The agency should consider whether additional recruitment and advertisement activities are necessary or appropriate to further merit system principles. If USAJOBS is not used to advertise the position, the agency must satisfy the requirements of 5 U.S.C. 3327(b) by providing OPM information about the position in the same format it usually would when posting a position on USAJOBS. A job announcement must include, at a minimum, the following information:

(1) The position title, series, grade level;

(2) The geographic location where the position will be filled;

(3) The starting salary of the position;

(4) The minimum qualifications of the position;

(5) Whether the position has promotion protentional to higher grade levels;

(6) Any other relevant information about the position such as telework opportunities, recruitment incentives, etc.;

(7) Specific information instructing applicants on how to apply;

(8) Equal employment opportunity statement (Agencies may use the recommended equal employment opportunity statement located on OPM's USAJOBS website.); and

(9) Reasonable accommodation statement.

(f) *Appointment type.* College graduates are appointed to career or career-conditional permanent positions in the competitive service.

(g) *Acquisition of competitive status.* A person appointed under this section acquires competitive status upon completion of probationary period in accordance with the provisions of subpart H of this part.

(h) *Tenure upon appointment.* A person appointed under paragraph (a) of this section becomes a career-conditional employee unless the appointee has already satisfied the requirements for career tenure or is exempt from the service requirement pursuant to § 315.201.

(i) *Numerical limit on the number of appointments.* (1) Except as provided in paragraph (i)(2) of this section, the total number of individuals that an agency may appoint under this authority during a fiscal year may not exceed 15 percent of the number of individuals that the agency appointed during the previous FY to a position in the competitive service classified in a professional or administrative occupational category, at the GS–11 level or below, or equivalent, under competitive examining procedures. An appointing agency may not count appointments made using direct hire authorities, non-competitive authorities, excepted service authorities, or selections under merit promotion authorities, when establishing the limit for a given fiscal year. In calculating this limitation, agencies must round up or down to the nearest whole number, if necessary, to eliminate a decimal place. Values ending in ''.5'' or more may be rounded up to the nearest whole number in determining an agency's cap limitation. Values ending in less than ''.5'' should be rounded down to the nearest whole number in determining an agency's cap limitation.

(2) During any given fiscal year, OPM may establish a lower limitation on the number of individuals that may be appointed under paragraph (i)(1) of this section based on any factor OPM

considers appropriate. OPM shall notify agencies via the OPM website to communicate any modification to the numerical limitation.

(j) *Reporting requirements.* (1) Not later than September 30 of each of the first three fiscal years beginning in FY 2020 an agency that makes an appointment under these provisions must report to Congress and to OPM on the impact of this authority for the fiscal year for which the report is submitted. OPM will provide written guidance, at the time this rule is published, describing the means by which agencies should collect this information, the timing of such collections, and the groups as to which information should be collected. An agency's report must contain the following information:

(i) The total number of individuals appointed by the agency under this authority by position title, series, grade, and geographic location;

(ii) The number of individuals appointed under this authority by the items identified in 5 U.S.C. 3115(g), and in OPM guidance;

(iii) The number of veterans appointed, as defined in 5 U.S.C. 2108;

(iv) Any numerical limitation established in paragraph (i) of this section;

(v) Recruitment sources, outreach, and recruitment activities used to fill positions;

(vi) The total number of individuals appointed by the agency during the applicable fiscal year to a position in the competitive service classified in a professional or administrative occupational category at the GS–11 level, or an equivalent level, or below;

(vii) The number of individuals appointed under the authority that have been separated to show a break down between involuntary and voluntary separations as well as the reasons for each type of separation;

(viii) Information on difficulties encountered when using the authority;

(2) OPM may request additional information from agencies on their use of this authority. An agency must include in its report to Congress and OPM any additional information required by OPM under this subsection.

(k) *Special provisions for Department of Defense.* These regulations do not preclude the Secretary of Defense from exercising authority to appoint a recent graduate under section 1106 of Public Law 114–328. Additionally, these regulations do not apply to the Department of Defense during the period section 1106 of Public Law 114–328 is in effect.

PART 330—RECRUITMENT, SELECTION, AND PLACEMENT (GENERAL)

■ 3. The authority citation for part 330 is revised to read as follows:

Authority: 5 U.S.C. 1104, 1302, 3301, 3302, 3304, and 3330; E.O. 10577, 3 CFR, 1954–58 Comp., p. 218; Section 330.103 also issued under 5 U.S.C. 3327; Section 330.104 also issued under sec. 2(d), Pub. L. 114–137, 130 Stat. 310; Subpart B also issued under 5 U.S.C. 3315 and 8151; Section 330.401 also issued under 5 U.S.C. 3310; Subparts F and G also issued under Presidential Memorandum on Career Transition Assistance for Federal Employees, September 12, 1995; Section 330.609 also issued under 5 U.S.C. 3115; Subpart G also issued under 5 U.S.C. 8337(h) and 8456(b); Section 330.707 also issued under 5 U.S.C. 3115 and 3116.

Subpart F—Agency Career Transition Assistance Plan (CTAP) for Local Surplus and Displaced Employees

■ 4. In § 330.609, add paragraph (ff) to read as follows:

§ 330.609 Exceptions to CTAP selection priority.

* * * * *

(ff) Make an appointment using the college graduate hiring authority under 5 U.S.C. 3115 and part 315 of this chapter.

* * * * *

Subpart G—Interagency Career Transition Assistance Plan (ICTAP) for Displaced Employees

■ 5. In § 330.707, add paragraph (x) to read as follows:

§ 330.707 Exceptions to ICTAP selection priority.

* * * * *

(x) Make an appointment using the college graduate hiring authority under 5 U.S.C. 3115 and part 315 of this chapter.

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[FR Doc. 2021–23871 Filed 11–4–21; 8:45 am]

BILLING CODE 6325–39–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2021–0134]

RIN 3150–AK67

List of Approved Spent Fuel Storage Casks: TN Americas LLC, TN–32 Dry Storage Cask, Certificate of Compliance No. 1021, Renewal of Initial Certificate and Amendment No. 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its spent fuel storage regulations by revising the TN Americas LLC, TN–32 Dry Storage Cask listing within the ''List of approved spent fuel storage casks'' to renew, for an additional 40 years, the initial certificate and Amendment No. 1 of Certificate of Compliance No. 1021. The renewal of the initial certificate and Amendment No. 1 revises the certificate of compliance's conditions and technical specifications to address aging management activities related to the structures, systems, and components of the dry storage system to ensure that these will maintain their intended functions during the period of extended storage operations. The scope of the Certificate of Compliance No. 1021 renewal includes spent fuel storage cask models TN–32, TN–32A, and TN–32B.

DATES: This direct final rule is effective January 19, 2022, unless significant adverse comments are received by December 6, 2021. If this direct final rule is withdrawn as a result of such comments, timely notice of the withdrawal will be published in the **Federal Register**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Comments received on this direct final rule will also be considered to be comments on a companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**.

ADDRESSES: Submit your comments, identified by Docket ID NRC–2021–0134, at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and

Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Christian Jacobs, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–6825, email: *Christian.Jacobs@nrc.gov* and Caylee Kenny, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–7150, email: *Caylee.Kenny@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Table of Contents:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0134 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0134. Address questions about NRC dockets to Dawn Forder, telephone: 301–415–3407, email: *Dawn.Forder@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.

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

B. Submitting Comments

Please include Docket ID NRC–2021–0134 in your comment submission. The NRC requests that you submit comments through the Federal rulemaking website at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

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

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

II. Rulemaking Procedure

This rule is limited to the renewal of the initial certificate and Amendment No. 1 of Certificate of Compliance No. 1021 and does not include other aspects of the TN Americas LLC, TN–32 Dry Storage Cask system design. The NRC is using the ''direct final rule procedure'' to issue this renewal because it represents a limited and routine change to an existing certificate of compliance that is expected to be non-controversial. Adequate protection of public health and safety continues to be reasonably assured. The amendment to the rule will become effective on January 19, 2022. However, if the NRC receives any significant adverse comments on this direct final rule by December 6, 2021, then the NRC will publish a document that withdraws this action and will subsequently address the comments received in a final rule as a response to the companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule, certificate of compliance, or technical specifications.

III. Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended, requires that ''[t]he Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the Nuclear Waste Policy Act states, in part, that ''[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule that added a new subpart K in part 72 of title 10 of the

Code of Federal Regulations (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L in 10 CFR part 72 entitled ''Approval of Spent Fuel Storage Casks,'' which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on March 20, 2000 (65 FR 14790), that approved the TN–32 Dry Storage Cask system design and added it to the list of NRC-approved cask designs in § 72.214 as Certificate of Compliance No. 1021.

IV. Discussion of Changes

On March 5, 2020, TN Americas LLC submitted a request to the NRC to renew, for an additional 40 years, the initial certificate and Amendment No. 1 of Certificate of Compliance No. 1021 for the TN–32 Dry Storage Cask system. TN Americas LLC supplemented its request on November 11, 2020; February 5, 2021; and March 17, 2021.

The renewal of the initial certificate and Amendment No. 1 was conducted in accordance with the renewal provisions in § 72.240. This section of the NRC spent fuel storage regulations authorizes the NRC to include any additional certificate conditions it deems necessary to ensure the safe operation of the cask during the certificate's renewal period. The NRC included three additional conditions to the renewal of the initial certificate of compliance and Amendment No. 1:

- The submittal of an updated final safety analysis report (UFSAR) to address aging management activities resulting from the renewal of the certificate of compliance. This condition ensures that the UFSAR changes are made in a timely fashion to enable general licensees using the storage system during the period of extended operation to develop and implement necessary procedures.
- The requirement that general licensees initiating or using spent fuel dry storage operations with the TN–32 Dry Storage Cask system ensure that their evaluations are included in the reports required by § 72.212, ''Conditions of general license issued under § 72.210.'' These reports will include appropriate considerations for the period of extended operation, a review of the UFSAR changes resulting from the certificate of compliance renewal, and a review of the NRC safety evaluation report (SER) related to the certificate of compliance renewal.
- The requirement that future amendments and revisions to this certificate of compliance include evaluations of the impacts to aging management activities to ensure that they remain adequate for any changes to the structures, systems, and components (SSCs).

The NRC made one corresponding change to the technical specifications for the initial certificate of compliance and Amendment No. 1. The change added a new section, which ensures that general licensees using the storage system develop procedures to address aging management activities required in the period of extended operation.

As documented in the preliminary SER, the NRC performed a safety evaluation of the proposed certificate of compliance renewal request. The NRC determined that this renewal does not change the cask design or fabrication requirements in the proposed certificate of compliance renewal request. The NRC determined that the design of the cask would continue to maintain confinement, shielding, and criticality control in the event of each evaluated accident condition. In addition, any resulting occupational exposure of offsite dose rates from the renewal of the initial certificate of compliance and Amendment No. 1 would remain well within the limits specified by 10 CFR part 20, ''Standards for Protection Against Radiation.'' Thus, the NRC found there will be no significant change in the types or amounts of any effluent released, no significant increase in the individual or cumulative radiation exposure, and no significant increase in the potential for or consequences from radiological accidents. In its SER for the renewal of the TN–32 Dry Storage Cask system, the NRC staff has determined that if the conditions specified in the certificate of compliance to implement these regulations are met, adequate protection of public health and safety will continue to be reasonably assured.

This direct final rule revises the TN–32 Dry Storage Cask listing in § 72.214 by renewing for 40 more years, the initial certificate and Amendment No. 1 of Certificate of Compliance No. 1021. The renewal consists of the changes previously described, as set forth in the renewed initial certificate and amendment and their revised technical specifications. The revised technical specifications are identified in the SER.

V. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this direct final rule, the NRC revises the TN Americas LLC TN–32 Dry Storage Cask design listed in § 72.214, ''List of approved spent fuel storage casks.'' This action does not constitute the establishment of a standard that contains generally applicable requirements.

VI. Agreement State Compatibility

Under the ''Agreement State Program Policy Statement'' approved by the Commission on October 2, 2017, and published in the **Federal Register** on October 18, 2017 (82 FR 48535), this rule is classified as Compatibility Category NRC—Areas of Exclusive NRC Regulatory Authority. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended, or the provisions of 10 CFR chapter I. Therefore, compatibility is not required for program elements in this category. Although an Agreement State may not adopt program elements reserved to the NRC, and the Category ''NRC'' does not confer regulatory authority on the State, the State may wish to inform its licensees of certain requirements by means consistent with the particular State's administrative procedure laws.

VII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885).

VIII. Environmental Assessment and Finding of No Significant Impact

Under the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' the NRC has determined that this direct final rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The NRC has made a finding of no significant impact on the basis of this environmental assessment.

A. The Action

The action is to amend § 72.214 to revise the TN–32 Dry Storage Cask listing within the ''List of approved spent fuel storage casks'' to renew, for

an additional 40 years, the initial certificate and Amendment No. 1 of Certificate of Compliance No. 1021.

B. The Need for the Action

This direct final rule renews the initial certificate and Amendment No. 1 of Certificate of Compliance No. 1021 for the TN Americas LLC, TN–32 Dry Storage Cask system design within the list of approved spent fuel storage casks to allow power reactor licensees to store spent fuel at reactor sites in casks with the approved modifications under a general license. Specifically, this rule extends the expiration date for the TN Americas LLC, TN–32 Dry Storage Cask certificate for an additional 40 years, allowing a reactor licensee to continue using it under general license provisions in an independent spent fuel storage installation to store spent fuel in dry casks in accordance with 10 CFR part 72.

C. Environmental Impacts of the Action

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent fuel under a general license in cask designs approved by the NRC. The potential environmental impact of using NRC-approved storage casks was analyzed in the environmental assessment for the 1990 final rule. The environmental assessment for this renewal of the initial certificate and Amendment No. 1 of Certificate of Compliance No. 1021 tiers off of the environmental assessment for the July 18, 1990, final rule. Tiering on past environmental assessments is a standard process under the National Environmental Policy Act of 1969, as amended. As required by § 72.240, applications for renewal of a spent fuel storage certificate of compliance design are required to demonstrate that SSCs important to safety will continue to perform their intended function for the requested renewal term. As discussed in the NRC's SER for the renewal of the initial certificate and Amendment No. 1, the NRC has approved conditions in the renewed initial certificate and Amendment No. 1 requiring the general licensee to implement the aging management activities described in the renewal application and incorporated into the UFSAR. These conditions ensure that the TN Americas LLC, TN–32 Dry Storage Cask system will continue to perform its intended safety functions and provide reasonable assurance of adequate protection of public health and safety throughout the renewal period.

Incremental impacts from continued use of the TN–32 Dry Storage Cask system under a general license for an additional 40 years are not considered significant. When the general licensee follows all procedures and administrative controls, including the conditions established because of this renewal, no effluents are expected from the sealed dry cask systems. Activities associated with cask loading and decontamination may result in some small incremental liquid and gaseous effluents, but these activities will be conducted under 10 CFR parts 50 and 52 reactor operating licenses, and effluents will be controlled within existing reactor site technical specifications. Because reactor sites are relatively large, any incremental offsite doses due to direct radiation exposure from the spent fuel storage casks are expected to be small, and when combined with the contribution from reactor operations, well within the annual dose equivalent of 0.25 mSv (25 mrem) limit to the whole body specified in § 72.104. Incremental impacts on collective occupational exposures due to dry cask spent fuel storage are expected to be only a small fraction of the exposures from operation of the nuclear power station.

The TN–32 Dry Storage Cask system is designed to mitigate the effects of design-basis accidents that could occur during storage. Design-basis accidents account for human-induced events and the most severe natural phenomena reported for the site and surrounding area. Postulated accidents analyzed for an independent spent fuel storage installation, the type of facility at which a holder of a power reactor operating license would store spent fuel in casks in accordance with 10 CFR part 72, can include tornado winds and tornado-generated missiles, a design-basis earthquake, a design-basis flood, an accidental cask drop, lightning effects, fire, explosions, and other incidents.

During the promulgation of the amendments that added subpart K to 10 CFR part 72 (55 FR 29181; July 18, 1990), the NRC staff assessed the public health consequences of dry cask storage accidents and sabotage events. In the supporting analyses for these amendments, the NRC determined that a release from a dry cask storage system would be comparable in magnitude to a release from the same quantity of fuel in a spent fuel storage pool. As a result of these evaluations, the NRC determined that, because of the physical characteristics of the storage casks and conditions of storage that include specific security provisions, the potential risk to public health and safety due to accidents or sabotage is very small.

Considering the specific design requirements for each accident or sabotage condition, the design of the cask would maintain confinement, shielding, and criticality control. If confinement, shielding, or criticality control are maintained, the environmental impacts from an accident would be insignificant.

There are no changes to cask design or fabrication requirements in the renewed initial certificate or Amendment No. 1. Because there are no significant design or process changes, any resulting occupational exposure or offsite dose rates from the implementation of the renewal of the initial certificate and Amendment No. 1 would remain well within the 10 CFR part 20 limits.

In summary, the proposed changes will not result in any radiological or nonradiological environmental impacts that significantly differ from the environmental impacts evaluated in the environmental assessment supporting the July 18, 1990, final rule. Compliance with the requirements of 10 CFR parts 20 and 72 would provide reasonable assurance that adequate protection of public health and safety will continue. The NRC, in its SER for the renewal of the TN–32 Dry Storage Cask system, has determined if the conditions specified in the certificate of compliance to implement these regulations are met, adequate protection of public health and safety will continue to be reasonably assured.

Based on the previously stated assessments and its SER for the requested renewal of the TN–32 Dry Storage Cask certificates, the NRC has determined that the expiration date of this system in 10 CFR 72.214 can be safely extended for an additional 40 years, and that commercial nuclear power reactor licensees can continue using the system during this period under a general license without significant impacts on the human environment.

D. Alternative to the Action

The alternative to this action is to deny approval of the renewal and not issue the direct final rule. Under this alternative, the NRC would either (1) require general licensees using the TN–32 Dry Storage Cask to unload the spent fuel from these systems and either return it to a spent fuel pool or reload it into a different dry storage cask system listed in § 72.214; or (2) require that users of the existing TN–32 Dry Storage Cask request site-specific licensing proceedings to continue storage in these systems.

The environmental impacts of requiring the licensee to unload the spent fuel and either return it to the spent fuel pool or re-load it into another NRC-approved cask system would result in increased radiological doses to workers. These increased doses would be due primarily to direct radiation from the casks while the workers unloaded, transferred, and re-loaded the spent fuel. These activities would consist of transferring the dry storage canisters to a cask-handling building, opening the canister lid welds, returning the canister to a spent fuel pool or dry transfer facility, removing the fuel assemblies, and re-loading them, either into a spent fuel pool storage rack or another NRC-approved dry storage system. In addition to the increased occupational doses to workers, these activities may also result in additional liquid or gaseous effluents.

Alternatively, users of the dry cask storage system would need to apply for a site-specific license. Under this option for implementing the no-action alternative, interested licensees would have to prepare, and the NRC would have to review, each separate license application, thereby increasing the administrative burden upon the NRC and the costs to each licensee.

In summary, the no-action alternative would entail either (1) more environmental impacts than the preferred action from transferring the spent fuel now in the TN–32 Dry Storage Cask; or (2) cost and administrative impacts from multiple licensing actions that, in aggregate, are likely to be the same as, or more likely greater than, the preferred action.

E. Alternative Use of Resources

Renewal of the initial certificate and Amendment No. 1 to Certificate of Compliance No. 1021 would result in no irreversible commitment of resources.

F. Agencies and Persons Contacted

No agencies or persons outside the NRC were contacted in connection with the preparation of this environmental assessment.

G. Finding of No Significant Impact

The environmental impacts of the action have been reviewed under the requirements in the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in subpart A of 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.'' Based on the foregoing environmental assessment, the NRC concludes that this direct final rule, ''List of Approved Spent Fuel Storage Casks: TN Americas LLC, TN–32 Dry Storage Cask, Certificate of Compliance No. 1021, Renewal of Initial Certificate and Amendment No. 1,'' will not have a significant effect on the human environment. Therefore, the NRC has determined that an environmental impact statement is not necessary for this direct final rule.

IX. Paperwork Reduction Act Statement

This direct final rule does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing collections of information were approved by the Office of Management and Budget, approval number 3150–0132.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid Office of Management and Budget control number.

X. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the NRC certifies that this direct final rule will not, if issued, have a significant economic impact on a substantial number of small entities. This direct final rule affects only nuclear power plant licensees and TN Americas LLC. These entities do not fall within the scope of the definition of small entities set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810).

XI. Regulatory Analysis

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent nuclear fuel under a general license in cask designs approved by the NRC. Any nuclear power reactor licensee can use NRC-approved cask designs to store spent nuclear fuel if (1) it notifies the NRC in advance; (2) the spent fuel is stored under the conditions specified in the cask's certificate of compliance; and (3) the conditions of the general license are met. A list of NRC-approved cask designs is contained in § 72.214. On March 20, 2000 (65 FR 14790), the NRC issued an amendment to 10 CFR part 72, with an effective date of April 19, 2000, that approved the TN Americas LLC TN–32 Dry Storage Cask by adding it to the list of NRC-approved cask designs in § 72.214.

On March 5, 2020, and as supplemented on November 11, 2020; February 5, 2021; and March 17, 2021, TN Americas LLC requested a renewal of the initial certificate and Amendment No. 1 of the TN–32 Dry Storage Cask system for an additional 40 years beyond the initial certificate term as discussed in Section IV, ''Discussion of Changes,'' of this document. Because TN Americas LLC filed its renewal application at least 30 days before the certificate expiration date of April 19, 2020, pursuant to the timely renewal provisions in § 72.240(b), the initial issuance of the certificate and Amendment No. 1 of Certificate of Compliance No. 1021 did not expire.

The alternative to this action is to deny approval of the renewal of the initial certificate and Amendment No. 1 of Certificate of Compliance No. 1021 and end this direct final rule. Under this alternative, the NRC would either (1) require general licensees using the TN–32 Dry Storage Cask system to unload spent fuel from these systems and return it to a spent fuel pool or reload it into a different dry storage cask system listed in § 72.214, or (2) require that users of the existing TN–32 Dry Storage Cask system request site-specific licensing proceedings to continue storage in these systems. Therefore, the no-action alternative would result in a significant burden on licensees and an additional inspection or licensing caseload on the NRC. In addition, the no-action alternative would entail either (1) more environmental impacts than the preferred action from transferring the spent fuel now in the TN–32 Dry Storage Cask system, or (2) cost and administrative impacts from multiple licensing actions that, in aggregate, are likely to be the same as, or more likely greater than, the preferred action.

Approval of this direct final rule is consistent with previous NRC actions. Further, as documented in the preliminary SER and environmental assessment, this direct final rule will have no adverse effect on public health and safety or the environment. This direct final rule has no significant identifiable impact or benefit on other government agencies. Based on this regulatory analysis, the NRC concludes that the requirements of this direct final rule are commensurate with the NRC's responsibilities for public health and safety and the common defense and security. No other available alternative is believed to be as satisfactory; therefore, this action is recommended.

XII. Backfitting and Issue Finality

The NRC has determined that the backfit rule (§ 72.62) does not apply to

this direct final rule. Therefore, a backfit analysis is not required. This direct final rule renews Certificate of Compliance No. 1021 for the TN Americas LLC TN–32 Dry Storage Cask system, as currently listed in § 72.214, to extend the expiration date of the initial certificate and Amendment No. 1 by 40 years. The renewed initial certificate and Amendment No. 1 consist of the changes previously described, as set forth in the revised certificate of compliance and technical specifications.

Extending the effective date of the initial certificate and Amendment No. 1 for 40 more years and requiring the implementation of aging management activities does not impose any modification or addition to the design of a cask system's SSCs, or to the procedures or organization required to operate the system during the initial 20-year storage period of the system, as authorized by the current certificate. General licensees that have loaded these casks, or that load these casks in the future under the specifications of the applicable certificate, may continue to store spent fuel in these systems for the initial 20-year storage period consistent with the original certificate. The aging management activities required to be implemented by this renewal are only required after the storage cask system's initial 20-year service period ends. As explained in the 2011 final rule that amended 10 CFR part 72 (76 FR 8872, Question I), the general licensee's authority to use a particular storage cask design under an approved certificate of compliance terminates 20 years after the date that the general licensee first loads the particular cask with spent fuel, unless the cask's certificate of compliance is renewed. Because this rulemaking renews the initial certificate and Amendment No. 1, and renewal is a separate licensing action voluntarily implemented by vendors, the renewal of the initial certificate and Amendment No. 1 is not an imposition of new or changed requirements from which these licensees would otherwise be protected by the backfitting provisions in § 72.62.

Even if renewal of the initial certificate and Amendment No. 1 of Certificate of Compliance No. 1021 could be considered a backfit, TN Americas LLC, as the holder of the certificate of compliance and vendor of the casks, is not protected by the backfitting provisions in § 72.62.

Unlike a vendor, general licensees using the existing systems subject to this renewal would be protected by the backfitting provisions in § 72.62 if the renewal constituted new or changed requirements applicable during the initial 20-year storage period. But, as previously explained, renewal of the initial certificate and Amendment No. 1 of Certificate of Compliance No. 1021 does not impose such requirements. The general licensee using the initial certificate or Amendment No. 1 of Certificate of Compliance No. 1021 may continue storing material in its respective cask systems for the initial 20-year storage period identified in the applicable certificate or amendment with no changes. If general licensees choose to continue to store spent fuel in the TN–32 Dry Storage Cask system after the initial 20-year period, these general licensees will be required to implement aging management activities for any cask systems subject to a renewed certificate of compliance, but such continued use is voluntary.

For these reasons, renewing the initial certificate and Amendment No. 1 of Certificate of Compliance No. 1021, and imposing the additional conditions previously discussed, does not constitute backfitting under § 72.62 or § 50.109(a)(1), or otherwise represent an inconsistency with the issue finality provisions applicable to combined licenses in 10 CFR part 52. Accordingly, the NRC has not prepared a backfit analysis for this rulemaking.

XIII. Congressional Review Act

This direct final rule is not a rule as defined in the Congressional Review Act.

XIV. Availability of Documents

The documents identified in the following table are available to interested persons, as indicated.

Document	ADAMS accession No.
TN Americas LLC Renewal Application for the TN–32 Dry Storage Cask Certificate of Compliance No. 1021, dated March 5, 2020.	ML20065J427
TN Americas LLC Response to Request for Additional Information for the Application for the Renewal of Certificate of Compliance No. 1021, dated November 11, 2020.	ML20316A030
Supplemental Response to Request for Additional Information for the TN Americas LLC Application for Renewal of the TN–32 Dry Storage Cask, Certificate of Compliance No. 1021, dated February 5, 2021.	ML21036A237
Supplemental Response to Request for Additional Information for the TN Americas LLC Application for Renewal of the TN–32 Dry Storage Cask, Certificate of Compliance No. 1021, dated March 17, 2021.	ML21076A040
User Need Memorandum for Rulemaking for Certificate of Compliance Renewal, Initial Issue (Amendment Number 0), Amendment Number 1 to TN–32 Dry Storage Cask, dated July 29, 2021.	ML21127A079
Preliminary Safety Evaluation Report for the TN–32 Dry Storage Cask Certificate of Compliance Renewal	ML21127A082
Proposed Certificate of Compliance No. 1021, Renewed Initial Certificate	ML21127A080
Proposed Technical Specifications,Appendix A, Certificate of Compliance No. 1021, Renewed Initial Certificate	ML21127A083
Proposed Certificate of Compliance No. 1021, Renewed Amendment No. 1	ML21127A081
Proposed Technical Specifications, Appendix A, Certificate of Compliance No. 1021, Renewed Amendment No. 1	ML21127A084

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2021–0134.

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 72:

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

■ 2. In § 72.214, Certificate of Compliance No. 1021 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1021.

Initial Certificate Effective Date: April 19, 2000, superseded by Renewed Initial Certificate on January 19, 2022.

Amendment Number 1 Effective Date: February 20, 2001, superseded by Renewed Amendment Number 1 on January 19, 2022.

SAR Submitted by: Transnuclear, Inc., now TN Americas LLC.

Renewal SAR Submitted by: TN Americas LLC.

SAR Title: Final Safety Analysis Report for the TN–32 Dry Storage Cask.

Docket Number: 72–1021.

Certificate Expiration Date: April 19, 2020.

Renewed Certificate Expiration Date: April 19, 2060.

Model Number: TN–32, TN–32A, TN–32B.

* * * * *

Dated: October 25, 2021.

For the Nuclear Regulatory Commission.

Daniel H. Dorman,

Executive Director for Operations.

[FR Doc. 2021–24216 Filed 11–4–21; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0611; Project Identifier MCAI–2021–00038–R; Amendment 39–21761; AD 2021–21–01]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2019–05–06, which applied to certain Airbus Helicopters Deutschland GmbH Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, and EC135T3 helicopters. AD 2019–05–06 required replacing the retaining ring, inspecting the hoist cable hook assembly, and, if necessary, replacing the elastomeric energy absorber. This AD continues to require the actions specified in AD 2019–05–06, and also requires a modification or replacement of the hoist cable hook assembly that would terminate the repetitive inspections and retaining ring replacements, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD was prompted by a report that a hook detached from the hoist cable. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 10, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 10, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of April 17, 2019 (84 FR 8961, March 13, 2019).

ADDRESSES: For EASA material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this material on the EASA website at *https://ad.easa.europa.eu.* For service information identified in this AD, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; phone: (972) 641–0000 or (800) 232–0323; fax: (972) 641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0611.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0611; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Jacob Fitch, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; phone: (817) 222–4130; email: *jacob.fitch@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0011, dated January 12, 2021 (EASA AD 2021–0011) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for Airbus Helicopters Deutschland GmbH (AHD) (formerly Eurocopter Deutschland GmbH, Eurocopter España S.A.) Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, EC135T3, EC635P2+, EC635P3, EC635T1, EC635T2+, and EC635T3 helicopters, all serial numbers up to 1276 inclusive. Model EC635P2+, EC635P3, EC635T1, EC635T2+, and EC635T3 helicopters are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those helicopters in the applicability.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2019–05–06, Amendment 39–19588 (84 FR 8961,

March 13, 2019) (AD 2019–05–06). AD 2019–05–06 applied to certain Airbus Helicopters Deutschland GmbH Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, and EC135T3 helicopters. The NPRM published in the **Federal Register** on August 3, 2021 (86 FR 41791). The NPRM was prompted by a report that a hook detached from the hoist cable. The NPRM proposed to continue to require the actions specified in AD 2019–05–06, as specified in an EASA AD. The NPRM also proposed to require a modification or replacement of the hoist cable hook assembly that would terminate the repetitive inspections and retaining ring replacements, as specified in an EASA AD.

The FAA is issuing this AD to address detachment of a hook from a hoist cable resulting in inflight failure of the hoist, which could result in injury to persons being lifted. See the MCAI for additional background information.

Discussion of Final Airworthiness Directive

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA received no comments on the NPRM or on the determination of the cost to the public.

Change to This Final Rule

The FAA has revised the format of paragraph (i)(5) of this AD.

Conclusion

The FAA reviewed the relevant data and determined that air safety and the public interest require adopting this final rule with the change described previously and minor editorial changes. The FAA has determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

The FAA also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0011 specifies procedures for replacing the retaining ring; inspecting the hoist cable hook assembly; replacing the elastomeric energy absorber; and modifying the hoist cable hook assembly or replacing an affected hoist with a serviceable hoist, which terminates the repetitive inspections and replacements.

This AD also requires Goodrich Service Bulletin No. 44301–10–17, Revision 4, dated July 26, 2017, which the Director of the Federal Register approved for incorporation by reference as of April 17, 2019 (84 FR 8961, March 13, 2019).

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

Other Related Service Information

Airbus Helicopters has issued Alert Service Bulletin No. ASB EC135–85A–069, Revision 0, dated August 2, 2017. The service information describes procedures for inspecting each affected hook assembly, replacing the retaining ring, and replacing the elastomeric energy absorber.

Costs of Compliance

The FAA estimates that this AD affects 341 helicopters of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained inspections and replacements of the retaining ring from AD 2019-05-06.	0.5 work-hour × $85 per hour = $42.50 per inspection cycle.	Minimal	$42.50 per inspection cycle	$14,492.50 per inspection cycle.
New modification	1 work-hour × $85 per hour = $85.	Negligible	$85	$28,985.

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement of the elastomeric energy absorber	0.5 work-hour × $85 per hour = $42.50	$2,152	$2,194.50

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2019–05–06, Amendment 39–19588 (84 FR 8961, March 13, 2019); and

■ b. Adding the following new AD:

2021–21–01 Airbus Helicopters Deutschland GmbH: Amendment 39–21761; Docket No. FAA–2021–0611; Project Identifier MCAI–2021–00038–R.

(a) Effective Date

This airworthiness directive (AD) is effective December 10, 2021.

(b) Affected ADs

This AD replaces AD 2019–05–06, Amendment 39–19588 (84 FR 8961, March 13, 2019) (AD 2019–05–06).

(c) Applicability

This AD applies to Airbus Helicopters Deutschland GmbH Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, and EC135T3 helicopters, all serial numbers up to 1276 inclusive, certificated in any category, with an affected hoist as identified in European Union Aviation Safety Agency (EASA) AD 2021–0011, dated January 12, 2021 (EASA AD 2021–0011).

(d) Subject

Joint Aircraft System Component (JASC) Code 2500, Cabin Equipment/Furnishings.

(e) Unsafe Condition

This AD was prompted by a report that a hook detached from the hoist cable. The FAA is issuing this AD to address detachment of a hook from a hoist cable resulting in inflight failure of the hoist, which could result in injury to persons being lifted.

(f) Compliance

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

(g) Retained Requirements of Paragraph (e) of AD 2019–05–06, With No Changes

This paragraph restates the requirements of paragraph (e) of AD 2019–05–06, with no changes. For Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, and EC135T3 helicopters: Within 90 hours time-in-service (TIS) after April 17, 2019 (the effective date of AD 2019–05–06) and thereafter at intervals not to exceed 180 hours TIS:

(1) Inspect the hook assembly and determine whether the elastomeric energy absorber has taken a permanent compression set by following the Accomplishment Instructions, paragraphs 2.A and 2.B, of Goodrich Service Bulletin No. 44301–10–17, Revision 4, dated July 26, 2017 (SB 44301–10–17). If the elastomeric energy absorber has taken a permanent compression set, replace the elastomeric energy absorber before the next hoist operation.

(2) Replace the retaining ring by following the Accomplishment Instructions, paragraphs 2.D through 2.K, of SB 44301–10–17.

(h) New Requirements

Except as specified in paragraph (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2021–0011.

(i) Exceptions to EASA AD 2021–0011

(1) Where EASA AD 2021–0011 refers to its effective date, this AD requires using the effective date of this AD.

(2) Paragraphs (1) and (2) of EASA AD 2021–0011 do not apply to this AD. The equivalent FAA requirements are specified in paragraph (g) of this AD.

(3) The ''Remarks'' section of EASA AD 2021–0011 does not apply to this AD.

(4) Where the service information referenced in EASA AD 2021–0011 specifies to discard certain parts, this AD requires removing those parts from service.

(5) Where paragraph (3) of EASA AD 2021–0011 specifies a method of accomplishment of certain actions, this AD requires replacing the text ''modify the affected hoist in accordance with the instructions of the modification ASB,'' with ''modify the affected hoist in accordance with paragraphs 3.B.1 and 3.B.2 of the Accomplishment Instructions of the modification ASB.''

(6) Where the service information referenced in EASA AD 2021–0011 specifies to use tooling, equivalent tooling may be used.

(7) Accomplishing the modification specified in paragraph (3) of EASA AD 2021–0011 or the replacement specified in paragraph (4) of EASA AD 2021–0011 terminates the repetitive actions required by paragraph (g) of this AD.

(8) Where paragraph (6) of EASA AD 2021–0011 refers to October 25, 2017 (the effective date of EASA AD 2017–0199), this AD requires using the effective date of this AD; and where paragraph (6) of EASA AD 2021–0011 specified to do actions ''as required by paragraph (1) of this [EASA] AD,'' for this AD, do the actions required by paragraph (g) of this AD.

(9) Paragraph (7) of EASA AD 2021–0011 does not apply to this AD. For this AD, for helicopters that do not have an affected hoist identified in paragraph (c) of this AD installed: As of the effective date of this AD, do not install an affected hoist identified in paragraph (c) of this AD on any helicopter.

(j) Special Flight Permit

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the helicopter to a location where the required actions can be done to the helicopter (if the operator elects to do so), provided the hoist is not used.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (l)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(l) Related Information

(1) Airbus Helicopters Alert Service Bulletin No. ASB EC135–85A–069, Revision 0, dated August 2, 2017, which is not incorporated by reference, contains additional information about the actions specified in paragraph (g) of this AD. To obtain a copy of this service information, contact Airbus Helicopters using the information in paragraph (m)(6) of this AD. You may view a copy of this service information at the FAA using the information in paragraph (m)(7) of this AD.

(2) For more information about this AD, contact Jacob Fitch, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; phone: (817) 222–4130; email: *jacob.fitch@faa.gov.*

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this

paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

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

(3) The following service information was approved for IBR on December 10, 2021.

(i) European Union Aviation Safety Agency (EASA) AD 2021–0011, dated January 12, 2021.

(ii) [Reserved]

(4) The following service information was approved for IBR on April 17, 2019 (84 FR 8961, March 13, 2019).

(i) Goodrich Service Bulletin No. 44301–10–17, Revision 4, dated July 26, 2017.

Note 1 to paragraph (m)(4)(i): Goodrich Service Bulletin No. 44301–10–17, Revision 4, dated July 26, 2017, is attached to Airbus Helicopters Alert Service Bulletin No. EC135–85A–069, Revision 0, dated August 2, 2017, which is not incorporated by reference in this AD.

(ii) [Reserved]

(5) For EASA AD 2021–0011, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* internet: *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(6) For Goodrich service information identified in this AD, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; phone: (972) 641–0000 or (800) 232–0323; fax: (972) 641–3775; or at *https://www.airbus.com/helicopters/services/support.html.*

(7) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0611.

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

Issued on September 27, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24154 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0604; Project Identifier 2019–CE–007–AD; Amendment 39–21771; AD 2021–21–11]

RIN 2120–AA64

Airworthiness Directives; Pacific Aerospace Limited Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Pacific Aerospace Limited Model 750XL airplanes. This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as insufficient clearance between the engine mount, the Beta control rod, and the inter-turbine temperature (ITT) sensing probe that could lead to chafing damage. This AD requires inspecting the engine mount, the temperature probe, and the reversing cable for damage, and taking any necessary corrective actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 10, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 10, 2021.

ADDRESSES: For service information identified in this final rule, contact the Civil Aviation Authority of New Zealand, Level 15, Asteron Centre, 55 Featherston Street, Wellington 6011; phone: +64 4 560 9400; fax: +64 4 569 2024; email: *info@caa.govt.nz.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0604.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0604; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the MCAI, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Mike Kiesov, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4144; fax: (816) 329–4090; email: *mike.kiesov@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain serial-numbered Pacific Aerospace Limited Model 750XL airplanes. The NPRM published in the **Federal Register** on July 28, 2021 (86 FR 40381). The NPRM was prompted by MCAI originated by the Civil Aviation Authority (CAA), which is the aviation authority for New Zealand. The CAA of New Zealand has issued AD DCA/750XL/35, effective date February 7, 2019 (referred to after this as ''the MCAI''), to correct an unsafe condition for certain Pacific Aerospace Limited Model 750XL airplanes. The MCAI states:

> DCA/750XL/35 is prompted by a review of the engine installation procedures, which identified that the clearance between the engine mount, the Beta control rod and the inter-turbine temperature (ITT) sensing probe could be insufficient and result in chafing damage. The [CAA] AD is issued to introduce the instructions in Pacific Aerospace Mandatory Service Bulletin (MSB) PACSB/XL/102 issue 2, dated 5 November 2018.

You may examine the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0604.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed Pacific Aerospace Limited Mandatory Service Bulletin PACSB/XL/102, Issue 2, dated November 5, 2018. The service information contains procedures for removing support clamps if installed by following the prior version of the service bulletin; inspecting the engine mount, the temperature probe, and the reversing cable for signs of chafing or damage; installing anti-chafing blade tape onto the engine mount tube; and obtaining further guidance for corrective actions. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Costs of Compliance

The FAA estimates that this AD affects 23 airplanes of U.S. registry. The FAA also estimates it will take about 2 work-hours per airplane to comply with the inspection and install anti-chafing blade tape. The average labor rate is $85 per work-hour and required parts would cost about $10 per airplane.

Based on these figures, the FAA estimates the inspection cost of this AD on U.S. operators to be $4,140 or $180 per airplane.

The damage found during the required inspection may vary from airplane to airplane. The FAA has no way of knowing how much damage each airplane may have or the cost to repair the damage for each airplane.

Contacting the CAA of New Zealand, if required, would take about 1 work-hour for an estimated cost of $85 per airplane.

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

Paperwork Reduction Act

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2021–21–11 Pacific Aerospace Limited: Amendment 39–21771; Docket No. FAA–2021–0604; Project Identifier 2019–CE–007–AD.

(a) Effective Date

This airworthiness directive (AD) is effective December 10, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pacific Aerospace Limited Model 750XL airplanes, serial numbers 101 through 215, 220, 8001, and 8002, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 7100, Power Plant System.

(e) Unsafe Condition

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as insufficient clearance between the engine mount, the Beta control rod, and the inter-turbine temperature (ITT) sensing probe that could lead to chafing damage. The FAA is issuing this AD to prevent damage to the engine mount, temperature probe, and the reversing cable. The unsafe condition, if not addressed, could result in chafing damage to the ITT system and binding of the Beta control rod.

(f) Actions and Compliance

(1) Unless already done, within 165 hours time-in-service after the effective date of this AD, inspect the engine mount, the temperature probe, and the reversing cable for damage, and, before further flight, take all necessary corrective actions and install anti-chafing blade tape onto the engine mount tube by following the Accomplishment Instructions in Pacific Aerospace Limited Mandatory Service Bulletin PACSB/XL/102, Issue 2, dated November 5, 2018.

(2) Where the service information states to contact Pacific Aerospace Limited if chafing or any damage is present on an engine mount, temperature probe, or reversing cable, this AD requires instead that you contact the Civil Aviation Authority (CAA) of New Zealand at the contact information in paragraph (i)(3) of this AD.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (h)(1) of this AD or by email at: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(h) Related Information

(1) For more information about this AD, contact Mike Kiesov, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4144; fax: (816) 329–4090; email: *mike.kiesov@faa.gov.*

(2) Refer to CAA of New Zealand AD No. DCA/750XL/35, effective date February 7, 2019, for more information. You may examine the CAA AD in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0604.

(i) Material Incorporated by Reference

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

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

(i) Pacific Aerospace Limited Mandatory Service Bulletin PACSB/XL/102, Issue 2, dated November 5, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact the Civil Aviation Authority of New Zealand, Level 15, Asteron Centre, 55 Featherston Street, Wellington 6011; phone: +64 4 560 9400; fax: +64 4 569 2024; email: *info@caa.govt.nz.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

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

Issued on October 8, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24085 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0671; Project Identifier 2019–SW–036–AD; Amendment 39–21768; AD 2021–21–08]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Leonardo S.p.a. Model AB139 and AW139 helicopters. This AD was prompted by a report of damage (burns) on the tail rotor blades (TRBs). This AD requires an inspection of each TRB for the general condition and any evidence of burns and replacement if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 10, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 10, 2021.

ADDRESSES: For material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* internet: *www.easa.europa.eu.* You may find this material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0671.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0671; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Jacob Fitch, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; phone: (817) 222–4130; email: *jacob.fitch@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0073, dated March 28, 2019 (EASA AD 2019–0073) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for Leonardo S.p.a. Model AB139 and AW139 helicopters.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Leonardo S.p.a. Model AB139 and AW139 helicopters. The NPRM published in the **Federal Register** on August 18, 2021 (86 FR 46162). The NPRM was prompted by a report of damage (burns) on the TRBs. The NPRM proposed to require an inspection of each TRB for the general condition and any evidence of burns and replacement if necessary, as specified in an EASA AD.

The FAA is issuing this AD to address damage (burns) on the TRBs. The unsafe condition, if not addressed, could result in loss of a TRB, possibly resulting in reduced control of the helicopter. See the MCAI for additional background information.

Discussion of Final Airworthiness Directive

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

The FAA reviewed the relevant data and determined that air safety and the

public interest require adopting this final rule as proposed, except for minor editorial changes. The FAA has determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

EASA AD 2019–0073 requires an inspection of each TRB for the general condition and any evidence of burns and replacement if necessary. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD, affects 138 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	3 work-hours × $85 per hour = $255 (4 blades)	$0	$255	$35,190

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement (per blade)	2 work-hours × $85 per hour = $170	$57,500 per blade	$57,670 per blade.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2021–21–08 Leonardo S.p.a.: Amendment 39–21768; Docket No. FAA–2021–0671; Project Identifier 2019–SW–036–AD.

(a) Effective Date

This airworthiness directive (AD) is effective December 10, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Leonardo S.p.a. Model AB139 and AW139 helicopters, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2019–0073, dated March 28, 2019 (EASA AD 2019–0073).

(d) Subject

Joint Aircraft Service Component (JASC) Codes: 3097, Ice/Rain Protection System Wiring; 6410, Tail Rotor Blades.

(e) Unsafe Condition

This AD was prompted by a report of damage (burns) on the tail rotor blades (TRBs). The FAA is issuing this AD to address damage (burns) on the TRBs. The unsafe condition, if not addressed, could result in loss of a TRB, possibly resulting in reduced control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2019–0073.

(h) Exceptions to EASA AD 2019–0073

(1) Where EASA AD 2019–0073 requires compliance in terms of flight hours, this AD requires using hours time-in-service.

(2) Where EASA AD 2019–0073 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where the service information required by EASA AD 2019–0073 specifies returning a part to the manufacturer, this AD does not include that requirement.

(4) This AD does not require the ''Remarks'' section of EASA AD 2019–0073.

(5) Where paragraph (2) of EASA AD 2019–0073 specifies to replace if there are burn signs or other damage, for this AD, other damage is defined as being consistent with wire overheat (*e.g.,* possible melted or exposed wires).

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2019–0073 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Special Flight Permit

Special flight permits, as described in 14 CFR 21.197 and 21.199, are not allowed.

(k) Alternative Methods of Compliance (AMOCs)

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

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

(l) Related Information

For more information about this AD, contact Jacob Fitch, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; phone: (817) 222–4130; email: *jacob.fitch@faa.gov.*

(m) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2019–0073, dated March 28, 2019.

(ii) [Reserved]

(3) For EASA AD 2019–0073, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* Internet: *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0671.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on October 7, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24153 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0659; Project Identifier 2018–SW–112–AD; Amendment 39–21763; AD 2021–21–03]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Leonardo S.p.a. Model A109A, A109A II, A109C, A109E, A109K2, A109S, AW109SP, A119, and AW119 MKII helicopters. This AD was prompted by a report of damage to a rigid connecting link (rod), and loosening of the nut on the upper rod end. This AD requires a visual inspection of the affected rods for damage, cracks, or abnormal play, and corrective actions if necessary, as specified in a European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 10, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 10, 2021.

ADDRESSES: For material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* internet: *www.easa.europa.eu.* You may find this material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0659.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0659; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Darren Gassetto, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; phone: (516) 228–7323; email: *darren.gassetto@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0280, dated December 17, 2018 (EASA AD 2018–0280) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for Leonardo S.p.a. (formerly Finmeccanica S.p.A., AgustaWestland S.p.A., Agusta S.p.A.; and AgustaWestland Philadelphia Corporation, formerly Agusta Aerospace Corporation) Model A109A, A109A II, A109C, A109E, A109K2, A109S, A109LUH, AW109SP, A119, and AW119 MKII helicopters. Model A109LUH helicopters are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those helicopters in the applicability.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR

part 39 by adding an AD that would apply to certain Leonardo S.p.a. Model A109A, A109A II, A109C, A109E, A109K2, A109S, AW109SP, A119, and AW119 MKII helicopters. The NPRM published in the **Federal Register** on August 13, 2021 (86 FR 44657). The NPRM was prompted by a report of damage to a rod, and loosening of the nut on the upper rod end. The NPRM proposed to require a visual inspection of the affected rods for damage, cracks, or abnormal play, and corrective actions if necessary, as specified in an EASA AD.

The FAA is issuing this AD to address damage to the rod, and loosening of the nut on the upper rod end, which could result in failure of the rod, possibly resulting in reduced control of the helicopter. See the MCAI for additional background information.

Discussion of Final Airworthiness Directive

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

The FAA reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. The FAA has determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

EASA AD 2018–0280 requires a visual inspection of the affected rods for damage, cracks, or evidence of abnormal play, and, depending on findings, any applicable corrective actions (which include replacing damaged or cracked connecting links and actions to address abnormal play).

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

Interim Action

The FAA considers this AD interim action. The inspection reports that are required by this AD will enable the manufacturer to obtain better insight into the nature, cause, and extent of the cracking, and eventually to develop final action to address the unsafe condition. Once final action has been identified, the FAA might consider further rulemaking.

Costs of Compliance

The FAA estimates that this AD affects 291 helicopters of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS *

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Visual Inspection	1 work-hour × $85 per hour = $85	$0	$85	$24,735

* Table does not include estimated costs for reporting.

The FAA estimates that it would take about 1 work-hour per product to comply with the reporting requirement in this AD. The average labor rate is $85 per hour. Based on these figures, the FAA estimates the cost of reporting the inspection results on U.S. operators to be $24,735, or $85 per product.

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	3 work-hour × $85 per hour = $255	Up to $2,351	Up to $2,606.

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

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Pkwy., Fort Worth, TX 76177–1524.

Authority for This Rulemaking

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

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds

necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2021–21–03 Leonardo S.p.a.: Amendment 39–21763; Docket No. FAA–2021–0659; Project Identifier 2018–SW–112–AD.

(a) Effective Date

This airworthiness directive (AD) is effective December 10, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Leonardo S.p.a. Model A109A, A109A II, A109C, A109E, A109K2, A109S, AW109SP, A119, and AW119 MKII helicopters, certificated in any category, with an affected part as identified in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD 2018–0280, dated December 17, 2018 (EASA AD 2018–0280).

(d) Subject

Joint Aircraft Service Component (JASC) Codes: 6700, Rotorcraft Flight Control; 6730, Rotorcraft Servo System.

(e) Unsafe Condition

This AD was prompted by a report of damage to a rigid connecting link (rod), and loosening of the nut on the upper rod end. The FAA is issuing this AD to address damage to the rod, and loosening of the nut on the upper rod end. The unsafe condition, if not addressed, could result in failure of the rod, possibly resulting in reduced control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2018–0280.

(h) Exceptions to EASA AD 2018–0280

(1) Where EASA AD 2018–0280 requires compliance in terms of flight hours, this AD requires using hours time-in-service.

(2) Where EASA AD 2018–0280 requires compliance from its effective date, this AD requires using the effective date of this AD.

(3) Where EASA AD 2018–0280 specifies action if ''any discrepancy'' is found, for this AD, discrepancies include damage, cracks, and evidence of abnormal play.

(4) Where the service information specified in EASA AD 2018–0280 specifies to ''replace the damaged connecting link'', for this AD, if any damage or cracks are found, remove the rod from service.

(5) Where the service information specified in EASA AD 2018–0280 specifies to ''contact Leonardo Helicopters'' if abnormal play is detected, for this AD if any abnormal play is detected, corrective action must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Leonardo S.p.a.'s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(6) Where EASA AD 2018–0280 requires reporting inspection results to Leonardo S.p.a. within 14 days after the effective date of EASA AD 2018–0280, this AD requires reporting inspection results at the applicable time in paragraph (h)(6)(i) or (ii) of this AD.

(i) If the inspection was done on or after the effective date of this AD: Submit the report within 14 days after the inspection.

(ii) If the inspection was done before the effective date of this AD: Submit the report within 14 days after the effective date of this AD.

(7) This AD does not require the ''Remarks'' section of EASA AD 2018–0280.

(i) Special Flight Permit

Special flight permits, as described in 14 CFR 21.197 and 21.199, are not allowed.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Related Information

For more information about this AD, contact Darren Gassetto, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; phone: (516) 228–7323; email: *darren.gassetto@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Aviation Safety Agency (EASA) AD 2018–0280, dated December 17, 2018.

(ii) [Reserved]

(3) For EASA AD 2018–0280, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* Internet: *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0659.

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

Issued on September 30, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24151 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0603; Project Identifier 2019–CE–006–AD; Amendment 39–21770; AD 2021–21–10]

RIN 2120–AA64

Airworthiness Directives; Pacific Aerospace Limited Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Pacific Aerospace Limited Model 750XL airplanes. This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as chafing damage in the port wing skin caused by the fuel system finger filters. This AD requires inspecting the wing internal skin for chafing and taking any necessary corrective actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 10, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 10, 2021.

ADDRESSES: For service information identified in this final rule, contact the Civil Aviation Authority of New Zealand, Level 15, Asteron Centre, 55 Featherston Street, Wellington 6011; phone: +64 4 560 9400; fax: +64 4 569 2024; email: *info@caa.govt.nz.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0603.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0603; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the MCAI, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Mike Kiesov, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4144; fax: (816) 329–4090; email: *mike.kiesov@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain serial-numbered Pacific Aerospace Limited Model 750XL airplanes. The NPRM published in the **Federal Register** on July 28, 2021 (86 FR 40384). The NPRM was prompted by MCAI originated by the Civil Aviation Authority (CAA), which is the aviation authority for New Zealand. The CAA of New Zealand has issued AD No. DCA/750XL/34, effective date February 7, 2019 (referred to after this as ''the MCAI''), to correct an unsafe condition for certain Pacific Aerospace Limited Model 750XL airplanes. The MCAI states:

> DCA/750XL/34 is prompted by a report of finding chafing damage in the port wing skin caused by the fuel finger filters. The [CAA] AD is issued to introduce inspection and repair requirements with the issue of Pacific Aerospace Mandatory Service Bulletin (MSB) PACSB/XL/099 issue 1, dated 16 January 2019.

The MCAI requires inspecting the wing internal skin for chafing and taking any necessary corrective actions.

You may examine the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0603.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information referenced above. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. This AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Pacific Aerospace Limited Mandatory Service Bulletin PACSB/XL/099, Issue 1, dated January 16, 2019. The service information contains procedures for removing and modifying the inspection panel assembly, inspecting the wing internal skin for chafing, repairing any chafing damage and replacing the fuel filter as necessary, and reinstalling the inspection panel assembly. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Costs of Compliance

The FAA estimates that this AD affects 23 airplanes of U.S. registry. The FAA also estimates that it would take about 5 work-hours per airplane to do the inspection and modification requirements of this proposed AD, and no parts would be necessary. Based on these figures, the FAA estimates the cost of the inspection and modification for U.S. operators to be $9,725, or $425 per airplane.

In addition, the FAA estimates that that any necessary follow-on actions for repair or replacement requirements of this AD will take about 6 work-hours and require parts costing $150, for a cost of $660 per airplane. The FAA has no way of determining the number of airplanes that may need these actions.

Authority for This Rulemaking

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

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

develop on products identified in this rulemaking action.

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2021–21–10 Pacific Aerospace Limited: Amendment 39–21770; Docket No. FAA–2021–0603; Project Identifier 2019–CE–006–AD.

(a) Effective Date

This airworthiness directive (AD) is effective December 10, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pacific Aerospace Limited Model 750XL airplanes, serial numbers 100 through 205, 207 through 213, and 8001, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 2800, Aircraft Fuel System.

(e) Unsafe Condition

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as chafing damage in the port wing skin caused by the fuel system finger filters. The FAA is issuing this AD to detect and correct chafing in the left hand (LH) wing leading edge tank skin, which if not detected and corrected, could result in a port wing fuel leak and lead to engine failure or fire.

(f) Compliance

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

(g) Required Actions

Within 165 hours time-in-service after the effective date of this AD, modify the LH inspection panel assembly and inspect the LH wing and fuel tank for chafing, and then, before further flight, repair any chafing and install the panels in accordance with the Accomplishment Instructions in Pacific Aerospace Limited Mandatory Service Bulletin PACSB/XL/099, Issue 1, dated January 16, 2019.

(h) Alternative Methods of Compliance (AMOCs)

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

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

(i) Related Information

(1) For more information about this AD, contact Mike Kiesov, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4144; fax: (816) 329–4090; email: *mike.kiesov@faa.gov.*

(2) Refer to Civil Aviation Authority (CAA) of New Zealand AD No. DCA/750XL/34, effective date February 7, 2019, for more information. You may examine the CAA AD in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0603.

(j) Material Incorporated by Reference

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

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

(i) Pacific Aerospace Limited Mandatory Service Bulletin PACSB/XL/099, Issue 1, dated January 16, 2019.

(ii) [Reserved]

(3) For service information identified in this AD, contact the Civil Aviation Authority of New Zealand, Level 15, Asteron Centre, 55 Featherston Street, Wellington 6011; phone: +64 4 560 9400; fax: +64 4 569 2024; email: *info@caa.govt.nz.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

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

Issued on October 8, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24084 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice: 11462]

RIN 1400–AF34

Visas: Nonimmigrant Visas

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State (Department) is amending its regulation governing nonimmigrant visas by amending its rules to remove references to the North American Free Trade Agreement (NAFTA) and replace them with references to the United States-Mexico-Canada Agreement (USMCA).

DATES: This final rule is effective on December 6, 2021.

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

SUPPLEMENTARY INFORMATION:

What changes is the Department making to 22 CFR 41.12 and 41.59?

The Department is amending 22 CFR 41.12 and 41.59 to remove references to NAFTA and replace them with references to the USMCA, which entered into force on July 1, 2020, and replaced NAFTA.

I. Regulatory Findings

Administrative Procedure Act

This rule is issued without prior notice and comment, with an effective

date 30 days after publication in the **Federal Register**, pursuant to the Administrative Procedure Act (''APA''), 5 U.S.C. 553(b)(3)(A) and (d)(2), because it re-states existing agency procedure or practice. As noted in the Preamble, the USMCA has replaced NAFTA, and visas previously issued to NAFTA professionals are now issued to USMCA professionals. Congress has amended 8 U.S.C. 1184(e) to replace references to NAFTA with references to the USMCA. The purpose of this rule is to make technical corrections to the regulatory text to replace references to NAFTA with references to USMCA, and consequently, it is not subject to the notice and comment rulemaking procedures set forth in 5 U.S.C. 553.

Regulatory Flexibility Act/Executive Order 13272: Small Business

Because this final rule is exempt from notice and comment rulemaking under 5 U.S.C. 553, it is exempt from the regulatory flexibility analysis requirements set forth by the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*

Unfunded Mandates Act of 1995

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

Congressional Review Act of 1996

This rule is not a major rule as defined by 5 U.S.C. 804(2), for purposes of congressional review of agency rulemaking. The Department does not believe that this rule will result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based companies to compete with foreign-based companies in domestic and import markets.

Executive Orders 12866, and 13563: Reducing Regulation and Controlling Regulatory Cost

The Department has reviewed this rule to ensure its consistency with the regulatory philosophy and principles set forth in Executive Orders 12866 and 13563, and has determined that the benefits of this regulation, *i.e.,* updating these rules to reflect the current agreement, outweigh any cost imposed by this rulemaking, which the Department assesses to be minimal.

Executive Orders 12372 and 13132: Federalism

While the USMCA itself may have an effect on States, this regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Therefore, this rule will not have federalism implications warranting the application of Executive Orders 12372 and 13132.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

The Department has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, the requirements of section 5 of Executive Order 13175 do not apply to this rulemaking.

Paperwork Reduction Act

This rule does not impose or revise any reporting or record-keeping requirements under the provisions of the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 41

Aliens, Passports and visas.

Accordingly, under the authority 8 U.S.C. 1104 and 22 U.S.C. 2651(a), 22 CFR part 41 is amended as follows:

PART 41—VISAS: DOCUMENTATION OF NONIMMIGRANTS UNDER THE IMMIGRATION AND NATIONALITY ACT, AS AMENDED

■ 1. The authority citation for part 41 continues to read as follows:

Authority: 8 U.S.C. 1101; 1102; 1104; 1182; 1184; 1185 note (section 7209 of Pub. L. 108–458, as amended by section 546 of Pub. L. 109–295); 1323; 1361; 2651a.

■ 2. Amend § 41.12 by revising the introductory text and revising the entries for ''TD'' and ''TN'' in the table to read as follows:

§ 41.12 Classification symbols.

A visa issued to a nonimmigrant alien within one of the classes described in this section shall bear an appropriate visa symbol to show the classification of the alien. The symbol shall be inserted in the space provided on the visa. The following visa symbols shall be used:

Symbol	Class	Section of law
*	* * * *	*
TN	USMCA Professional	214(e)(1)
TD	Spouse or Child of a USMCA Professional.	214(e)(1)
*	* * * *	*

■ 3. Revise § 41.59 to read as follows:

§ 41.59 Professionals under the United States-Mexico-Canada Agreement (USMCA).

(a) *Requirements for classification as a USMCA professional.* An alien shall be classifiable under the provisions of INA 214(e) if:

(1) The consular officer is satisfied that the alien qualifies under the provisions of that section; and

(2) The alien shall have presented to the consular officer sufficient evidence of an offer of employment in the United States requiring employment of a person in a professional capacity consistent with Section D and Appendix 2 of Annex 16–A of Chapter 16 of the USMCA and sufficient evidence that the alien possesses the credentials of that profession as listed in said appendix; or

(3) The alien is the spouse or child of an alien so classified in accordance with paragraph (a)(2) of this section and is accompanying or following to join the principal alien.

(b) *Visa validity.* The period of validity of a visa issued pursuant to paragraph (a) of this section may not exceed the period established on a reciprocal basis.

(c) *Temporary entry.* Temporary entry means an entry into the United States without the intent to establish permanent residence. The alien must satisfy the consular officer that the proposed stay is temporary. A temporary period has a reasonable, finite end that does not equate to permanent residence. The circumstances surrounding an application should reasonably and convincingly indicate that the alien's temporary work assignment in the United States will end predictably and that the alien will depart upon completion of the assignment.

(d) *Labor disputes.* Citizens of Canada or Mexico shall not be entitled to classification under this section if the Secretary of Homeland Security and the Secretary of Labor have certified that:

(1) There is in progress a strike or lockout in the course of a labor dispute in the occupational classification at the place or intended place of employment; and

(2) The alien has failed to establish that the alien's entry will not affect

adversely the settlement of the strike or lockout or the employment of any person who is involved in the strike or lockout.

Kevin E. Bryant,

Acting Director, Office of Directives Management, Department of State.

[FR Doc. 2021–24045 Filed 11–4–21; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2021–0671]

Special Local Regulations; Savannah Harbor Boat Parade of Lights and Fireworks, Savannah River, Savannah, GA

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Captain of the Port Savannah will enforce the special local regulation for the Savannah Harbor Boat Parade of Lights and Fireworks from 5:00 p.m. until 10:00 p.m. on November 27, 2021. This action is necessary to ensure safety of life on navigable waters of the Savannah River during the Savannah Harbor Boat Parade of Lights and Fireworks displays. During the enforcement period, no person or vessel may enter, transit through, anchor in, or remain within the designated area unless authorized by the Captain of the Port Savannah or a designated representative.

DATES: The regulations in 33 CFR 100.701, table 1 to § 100.701, paragraph (d), Item 4, will be enforced from 5 p.m. until 10 p.m., on November 27, 2021.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LT Alex McConnell, Marine Safety Unit Savannah Office of Waterways Management, Coast Guard; telephone 912–652–4353, extension 240, or email *Alexander.W.McConnell@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation for the Savannah Harbor Parade of Lights and Fireworks in 33 CFR 100.701 Table 1 to § 100.701, paragraph (d), Item 4, from 5 p.m. until 10 p.m., on November 27, 2021. Under the provisions of 33 CFR 100.701, all persons and vessels are prohibited from entering the regulated area unless they receive permission to do so from the Captain of the Port Savannah, or designated representatives. This action is to provide notice of enforcement action of the regulated area that will encompass the Savannah River in Savannah, GA from the Talmadge Bridge near River Street, coordinates 32°05′20″ N, 081°05′56.3″ W, and proceeding down river to a line drawn at 146 degrees true from day board 62, approximate coordinates are: 32°04′48.7″ N, 081°04′47.9″ W.

Spectator vessels may safely transit outside the regulated area, but may not anchor, block, loiter in, impede the transit of festival participants or official patrol vessels or enter the regulated area without approval from the Captain of the Port Savannah or a designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation. In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide notice of the regulated area via Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

K.A. Broyles,

Commander, U.S. Coast Guard, Captain of the Port, Savannah, GA.

[FR Doc. 2021–24076 Filed 11–4–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2021–0596]

RIN 1625–AA09

Drawbridge Operation Regulation; Ogeechee River, Richmond Hill, GA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is removing the existing drawbridge operation regulation for the Ogeechee River. The District Bridge Manager has determined that the waterway at mile 30.7, is an Advance Approved Waterway per the regulation. The railroad bridge at mile, 30.7 is being converted to a fixed bridge and the highway bridge at mile, 37.8 was removed from the waterway. The drawbridge operating regulation for the Ogeechee River is no longer applicable or necessary.

DATES: This rule is effective November 5, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0596. In the ''SEARCH'' box and click ''SEARCH.'' In the Document Type column, select ''Supporting & Related Material''.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Ms. Jennifer Zercher, Bridge Management Specialist, Seventh Coast Guard District, telephone 305–415–6740, email *Jennifer.N.Zercher@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
Pub. L. Public Law
§ Section
GA Georgia
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this final 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), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the waterway at mile 30.7 was designated as an Advance Approved Waterway in June 2021. The Seaboard System Railroad Bridge, mile 30.7, has not had a request to open in the past 40 years, is being rehabilitated and converted to a fixed bridge. The Highway Bridge, mile 37.8, was removed from the waterway. Therefore, regulation 33 CFR 117.367 is no longer applicable and shall be removed from publication. It is unnecessary to publish an NPRM because this regulatory action does not purport to place any restrictions on mariners but rather removes a restriction that has no further use or value.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**. The waterway is designated as Advance Approved, the Highway Bridge was removed from the waterway and the Seaboard System Railroad Bridge is

being rehabilitated and converted to a fixed bridge. This rule merely requires an administrative change to the **Federal Register**, in order to omit a regulatory requirement that is no longer applicable or necessary. Therefore, a delayed effective date is unnecessary.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499.

The Ogeechee River at mile 30.7, was designated as an Advance Approved Waterway per 33 CFR 115.70 in June 2021. The Seaboard System Railroad Bridge, mile 30.7, is being coverted to a fixed bridge and the Highway Bridge, mile 37.8, was removed from the waterway. The Advance Approved determination and the elimination of the removable span necessitates the removal of drawbridge operation regulation, 33 CFR 117.367, which pertains to the waterway and the former drawbridges.

The purpose of this rule is to remove 33 CFR 117.367 which refers to the Ogeechee River, from the Code of Federal Regulations since the waterway is designated as an Advance Approved Waterway at mile 30.7, the railroad bridge it governs is no longer able to be opened and the highway bridge was removed from the waterway.

IV. Discussion of Final Rule

The Coast Guard is removing regulation 33 CFR 117.367 and the regulatory burden related to the draw operations for a bridge that is no longer in existence and a bridge that is no longer a drawbridge. This Final Rule seeks to update the Code of Federal Regulations by removing language that governs the Ogeechee River. This change does not affect waterway or land traffic.

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 protesters.

A. Regulatory Planning and Review

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

This regulatory action determination is based on the fact that the waterway is designated as Advanced Approved, the railroad bridge is being converted to a fixed bridge and the highway bridge was removed from the waterway. The removal of the operating schedule from 33 CFR 117 Subpart B will have no effect on the movement of waterway or land traffic.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 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 bridge may be small entities, for the reasons stated in section V.A above this final rule would 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 contact 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 calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Government

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 Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series) which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). The Coast Guard has 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 promulgates the operating regulations or procedures for drawbridges and is categorically excluded from further review, under paragraph L49, of Chapter 3, Table 3–1, of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact 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 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

§ 117.367 [Removed]

■ 2. Remove § 117.367.

Dated: October 29, 2021.

Brendan C. McPherson,

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

[FR Doc. 2021–24087 Filed 11–4–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0745]

RIN 1625–AA00

Safety Zone; Potomac River, Between Charles County, MD and King George County, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is revising a temporary safety zone that was established for certain waters of the Potomac River. This action is necessary to provide for the safety of persons, and the marine environment from the potential safety hazards associated with construction operations at the new Governor Harry W. Nice/Senator Thomas ''Mac'' Middleton Memorial (US–301) Bridge, which will occur from 7 a.m. on November 2, 2021, through 8 p.m. on December 31, 2021. This rule will prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port, Sector Maryland-National Capital Region or a designated representative.

DATES: This rule is effective without actual notice from November 5, 2021 through December 31, 2021. For the purposes of enforcement, actual notice will be issued from November 2, 2021, until November 5, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0745 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Samuel Danus, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard: telephone 410–576–2519, email *Samuel.M.Danus@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
§ Section
TFR Temporary Final Rule
U.S.C. United States Code

II. Background Information and Regulatory History

On September 10, 2021, Skanska-Corman-McLean, Joint Venture, notified the Coast Guard that the company will continue to set 200-ton pre-cast fender ring elements at the new Governor Harry W. Nice/Senator Thomas ''Mac'' Middleton Memorial (US–301) Bridge at Piers 43 and 44, which are adjacent on either side of the federal navigation channel from September 13, 2021 through December 31, 2021. In response, on September 17, 2021, the Coast Guard issued a TFR; request for comments, Safety Zone; Potomac River, Between Charles County, MD and King George County, VA (86 FR 52826). There, we stated why we issued the TFR, and invited comments on our regulatory action related to this bridge construction activity due to the duration of the rule. During the comment period that ended October 25, 2021, we received 5 comments. The Coast Guard has amended this rule based on these comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this amended rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to respond to the potential safety hazards associated with construction operations at the new Governor Harry W. Nice/Senator Thomas ''Mac'' Middleton Memorial (US–301) Bridge conducted within the federal navigation channel.

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 has determined that potential hazards associated with bridge construction starting November 2, 2021, will be a safety concern for anyone within the federal navigation channel at the new Governor Harry W. Nice/Senator Thomas ''Mac'' Middleton Memorial (US–301) Bridge construction site. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the bridge is being constructed.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received 5 comments to the rule. Two commenters expressed their support of the zone, including the temporary safety zone's importance to protecting the marine environment. We concur, as stated in Section III, the rule is needed to protect personnel, vessels, and the marine environmental in the navigable waters within the safety zone.

The remaining 3 comments were provided by the bridge contractor, Skanska-Corman-McLean, Joint Venture, who provided revised dates for work requiring the continuous 24/7 enforcement of the zone for certain periods. One comment stated that the contruction of protective fender rings around Piers 43 and 44, on either side of the federal channel, was scheduled to occur October 25, 2021, through October 29, 2021. However, the contractor provided a subsequent comment, eight days later that revised the dates for this activity to 7 a.m. on November 4, 2021, through 8 p.m. on November 6, 2021, and 7 a.m. November 8, 2021, through 8 p.m. November 10, 2021. In addition, the final comment provided by the bridge contractor stated work required to set structural steel across the federal channel, originally scheduled to occur in November 2021, is now scheduled to occur 7 a.m. on December 6, 2021 through 8 p.m. on December 18, 2021.

Based on the comments provided by the contractor, the Coast Guard is

amending the regulatory text of this rule. The work described by the contractor requires the movement in and anchoring at multiple points of a large crane in the channel, as well as, nighttime diver work. This operation will impede vessels requiring the use of the channel. Although the setting of structural steel across the channel was not discussed in our original rule (86 FR 52826), this activity coincides with the original rule's effective dates and requires the same safety zone. Due to the nature of the work and susceptibility to rescheduling due to weather, equipment readiness, material availability or other issues resulting in construction delays, the Coast Guard is amending the regulatory text of the regulation to state that the exact dates and times of enforcement will be announced to the public by Broadcast Notice to Mariners, Local Notice to Mariners or other appropriate means. All other aspects of the original rule remain unchanged other than the correction of a scrivener's error in the title to paragraph (g).

This amended rule establishes a temporary safety zone from 7 a.m. on November 2, 2021, through 8 p.m. December 31, 2021. The safety zone will cover all navigable waters of the Potomac River, encompassed by a line connecting the following points beginning at 38°21′50.96″ N, 076°59′22.04″ W, thence south to 38°21′43.08″ N, 076°59′20.55″ W, thence west to 38°21′41.00″ N, 076°59′34.90″ W, thence north to 38°21′48.90″ N, 076°59′36.80″ W, and east back to the beginning point, located between Charles County, MD and King George County, VA. The temporary safety zone is approximately 450 yards in width and 270 yards in length.

The bridge owner will post a sign facing the northern and southern approaches of the navigation channel labeled ''BRIDGE WORK—DANGER—STAY AWAY'' affixed to the sides of the on-scene marine equipment and vessels operating within the area of the safety zone. *Marine equipment* means any vessel, barge or other equipment operated by Skanska-Corman-McLean, Joint Venture, or its subcontractors. This notice will consist of a diamond shaped sign (minimum 4 feet by 4 feet) with a 3-inch orange retro reflective border. The word ''DANGER'' will be 10 inch black block letters centered on the sign with the words ''BRIDGE WORK'' and ''STAY AWAY'' in 6 inch black block letters placed above and below the word ''DANGER,'' respectively, on a white background.

While the safety zone is effective from 7 a.m. on November 2, 2021, through 8 p.m. December 31, 2021, in most circumstances, the safety zone will be enforced 7 a.m. until 8 p.m., daily, Monday through Saturday. There will be periods of continuous 24/7 enforcement due to the nature of certain construction activites. The public will be advised of these periods through Notice to Mariners and other appropriate means, at least 2–5 days in advance.

The duration of the zone is intended to protect personnel and the marine environment in these navigable waters while the tub sections are being set at the new Governor Harry W. Nice/Senator Thomas ''Mac'' Middleton Memorial (US–301) Bridge at Piers 43 and 44, which are adjacent on either side of the federal navigation channel. Except for marine equipment and vessels operated by Skanska-Corman-McLean, Joint Venture, or its subcontractors, no vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

Designated representative means any Coast Guard commissioned, warrant, or petty officer, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Maryland-National Capital Region (COTP) in the enforcement of the safety zone. To seek permission to enter, contact the COTP or the COTP's representative by telephone number 410–576–2693 or on Marine Band Radio VHF–FM channel 16 (156.8 MHz). 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.

The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by Federal, State, and local agencies.

The COTP will notify the public that the safety zone will be enforced by all appropriate means to the affected segments of the public, as practicable, in accordance with 33 CFR 165.7(a).

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on size and duration of the safety zone. The temporary safety zone is approximately 450 yards in width and 270 yards in length. We anticipate that there will be no vessels that are unable to conduct business. Excursion vessels and commercial fishing vessels are not impacted by this rulemaking. Excursion vessels do not operate in this area, and commercial fishing vessels are not impacted because of their draft. Some towing vessels may be impacted, but bridge project personnel have been conducting outreach throughout the project in order to coordinate with those vessels. Vessel traffic not required to use the navigation channel will be able to safely transit around the safety zone. Such vessels may be able to transit to the east of the federal navigation channel, as similar vertical clearance and water depth exist under the next bridge span to the east. This safety zone will impact a small designated area of the Potomac River for 60 days, but coincides with the non-peak season for recreational boating.

B. Impact on Small Entities

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

While some owners or operators of vessels intending to transit the temporary 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 temporary safety zone lasting 60 total days that will prohibit entry within a portion of the Potomac 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. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T05–0745 to read as follows:

§ 165.T05–0745 Safety Zone; Potomac River, Between Charles County, MD and King George County, VA.

(a) *Location.* The following area is a safety zone: All navigable waters of the Potomac River, encompassed by a line connecting the following points beginning at 38°21′50.96″ N, 076°59′22.04″ W, thence south to 38°21′43.08″ N, 076°59′20.55″ W, thence west to 38°21′41.00″ N, 076°59′34.90″ W, thence north to 38°21′48.90″ N, 076°59′36.80″ W, and east back to the beginning point, located between Charles County, MD and King George County, VA. These 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 any Coast Guard commissioned, warrant, or petty officer, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Maryland-National Capital Region (COTP) in the enforcement of the safety zone.

Marine equipment means any vessel, barge or other equipment operated by Skanska-Corman-McLean, Joint Venture, or its subcontractors.

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

(2) To seek permission to enter, contact the COTP or the COTP's representative by telephone number 410–576–2693 or on Marine Band Radio VHF–FM channel 16 (156.8 MHz). Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement officials.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by Federal, State, and local agencies.

(e) *Enforcement.* This safety zone will be enforced during the period described in paragraph (f) of this section. A ''BRIDGE WORK—DANGER—STAY AWAY'' sign facing the northern and southern approaches of the navigation channel will be posted on the sides of the marine equipment on-scene within the location described in paragraph (a) of this section.

(f) *Enforcement period.* (1) The section will be enforced from 7 a.m. on November 2, 2021, through 8 p.m. December 31, 2021.

(2) The public will be advised of the status of the safety zone, to include dates and times, by Broadcast Notice to

Mariners, Local Notice to Mariners or other appropriate means.

Dated: November 1, 2021.

David E. O'Connell,

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

[FR Doc. 2021–24271 Filed 11–4–21; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2021–0262; FRL–9163–02–R8]

Approval and Promulgation of Implementation Plans; Colorado; Revisions to Regulation Number 7; Aerospace, Oil and Gas, and Other RACT Requirements for the 2008 8-Hour Ozone Standard for the Denver Metro/North Front Range Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Subject to certain exceptions, the Environmental Protection Agency (EPA) is approving State Implementation Plan (SIP) revisions submitted by the State of Colorado on May 14, 2018, May 8, 2019, May 13, 2020 and March 22, 2021. The revisions are to Colorado Air Quality Control Commission (Commission or AQCC) Regulation Number 7 (Reg. 7). The revisions to Reg. 7 address Colorado's SIP obligation to require reasonably available control technology (RACT) for sources covered by the 2016 oil and natural gas control techniques guidelines (CTG or CTGs) for nonattainment areas classified as Moderate and above under the 2008 ozone National Ambient Air Quality Standard (NAAQS); update RACT requirements for major sources of volatile organic compounds (VOC) and nitrogen oxides (NO_X); reorganize the regulation; add incorporation by reference dates to rules and reference methods; and make typographical, grammatical, and formatting corrections. Also, the EPA is finalizing approval of the State's negative declaration that there are no sources in the Denver Metro/North Front Range (DMNFR) Area subject to the aerospace CTG, which was conditionally approved in our February 24, 2021 rulemaking. Finally, we are taking no action today on several specific portions of the State submittals, as further explained below. The EPA is issuing this final rule pursuant to the Clean Air Act (CAA).

DATES: This rule is effective on December 6, 2021.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2021–0262. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Abby Fulton, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–IO, 1595 Wynkoop Street, Denver, Colorado 80202–1129, telephone number: (303) 312–6563, email address: *fulton.abby@epa.gov.*

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

I. Background

The background for this action is discussed in detail in our June 22, 2021 proposal.[1] In that document we proposed to approve various revisions to the Colorado SIP that were submitted to the EPA on May 14, 2018, May 8, 2019, May 13, 2020 and March 22, 2021. In particular, we proposed to approve certain Reg. 7 rules to meet the 2008 8-hour ozone NAAQS oil and gas CTG RACT requirements for Moderate nonattainment areas that were not acted on in our July 3, 2018[2] and February 24, 2021[3] rulemakings. We also proposed to approve certain area source rules as meeting the 2008 8-hour ozone NAAQS RACT requirements for Serious nonattainment areas. Additionally, we proposed finalizing approval of the State's negative declaration that there are no sources in the DMNFR Area subject to the aerospace CTG, which was conditionally approved in our February 24, 2021[4] rulemaking. The factual and legal background for this action is discussed in detail in our June 22, 2021 proposed approval. The proposal provides a detailed description of the revisions and the rationale for the EPA's proposed actions.

II. Comments

We received comments on the proposal from several commenters. One comment was a request to set up an air monitoring station near the Denver International Airport where there is oil and natural gas drilling activity. This comment is outside the scope of this action.

One set of relevant comments was submitted by the Center for Biological Diversity, Earthworks, and the Sierra Club. The comments were related to compliance with the CAA, CTGs as guidance documents, requirements that constitute RACT, suggested RACT for specific emission points in Colorado's submittal, enforceability, and CAA section 110(l). A summary of the comments and the EPA's responses are provided in the Response to Comments Document, which is contained within the docket for this action.

One specific comment received was related to periodic testing and monitoring to demonstrate compliance with the 95% control efficiency for control devices.[5] Upon further evaluation, the EPA determined that Colorado's SIP submissions were deficient for RACT purposes because Colorado did not include recommended provisions that are in the CTG concerning periodic performance testing for combustion devices controlling emissions from storage tanks and centrifugal compressors. Therefore, in this final action, the EPA is not acting on the following submitted revisions: Reg. 7, Section XII. J.1.[6] from the May 14, 2018 submittal for centrifugal compressors; Sections I.D., I.E, and I.F. from the May 13, 2020 submittal for storage tanks; and I.J.1. for centrifugal compressors. The EPA proposed to approve these portions of the respective SIP submittals in our June 22, 2021 proposal. These portions of these SIP

[1] 86 FR 32656.

[2] Final Rule, Approval and Promulgation of State Implementation Plan Revisions; Colorado; Attainment Demonstration for the 2008 8-Hour Ozone Standard for the Denver Metro/North Front Range Nonattainment Area, and Approval of Related Revisions, 83 FR 31068, 31069–31072.

[3] Final Rule, Approval and Promulgation of Implementation Plans; Colorado; Revisions to Regulation Number 7 and RACT Requirements for 2008 8-Hour Ozone Standard for the Denver Metro/North Front Range Nonattainment Area, 86 FR 11125, 11126–11127.

[4] 86 FR 11125.

[5] *See* comment and response number 16 in the ''Response to Comments for the **Federal Register** Notice on Approval and Promulgation of Implementation Plans; Colorado; Revisions to Regulation Number 7; Aerospace, Oil and Gas, and Other RACT Requirements for 2008 8-Hour-Ozone Standard for the Denver Metro/North Front Range Nonattainment Area'' document. Contained within the document for this section.

[6] Since renumbered to Colorado Reg. 7, Part D, Section I.J.1.

submittals will be acted on at a later date.

III. Final Action

The EPA is approving submitted revisions to Sections II, XII, and XVIII of Reg. 7 from the State's May 14, 2018 and May 8, 2019 submittals and Parts A through E from the State's May 13, 2020 submission as shown in Table 1, except for those revisions we are not acting on as represented in Table 2. We are approving Colorado's determination that the above rules constitute RACT for the specific categories addressed in Table 3.

TABLE 1—LIST OF COLORADO REVISIONS TO REG. 7 THAT THE EPA IS APPROVING IN THIS ACTION

Revised sections in May 14, 2018, May 8, 2019 and May 13, 2020 submittals for approval
May 14, 2018 Submittal:
II.B, XII.A.2, XII.B.1.–B.3., XII.B.6–B.13, XII.B.15–B.21., XII.B.24.–B.25., XII.C.1.c.–1.e., XII.C.1.e.(iv), XII.F.3.a.(i)–a.(x), XII.F.5., XII.F.5.c–G.1., XII.G.3–G.4., XII.H.3., XII.H.6.a., XII.I., XII.I.5., XII.J., XII.J.2–2.e., XII.K–K.5., XII.L.–L.8.a.(v), XVIII, XVIII.B.1.–B.3., XVIII.B.5, XVIII.B.7.–B.11., XVIII.C.–C.2.c.(ii), XVIII.D.–D.2.b., and XVIII.E.–E.2.c.
May 8, 2019 Submittal:
XII.B.12.–B.13, XII.B.20., XII.G.3., XII.J.2.e., XII.K.5., XVIII.B.1., XVIII.B.5., XVIII.B.7.–B.9., and XVIII.D.1.b.
May 13, 2020 Submittal:
Outline of Regulation, PART A, I.A.1.c., I.B.1.c., I.B.2.h., II.B., PART B, I.–I.C., II.–II.B., III.–III.B., IV.–IV.D.4.e., V.–V.C., VI.–VI.C.4.c.(ii), VII.–VII.B.2.b., Appendix B.II., Appendix B.V., Appendix B.VIII., Appendix C, PART C, I.–I.O.5.a.(v), II.–II.F.6.j., III.–III.B.3.b., IV–IV.B.5.c.(iii)(B), V.–V.C.1., Appendix D (renumbering), Appendix E (renumbering), PART D, I.–I.B.27., I.B.29.–I.C.1.e., I.C.1.e.(iii)–e.(iv), I.C.2.–2.a.(v), I.G.–I.H.1., I.H.3.–I.I.5., I.J.2.–I.L.8.a.(v)., II.C., II.C.1.,II.C.1.b.(ii)–(ii)(B), II.F, III.–III.B.3., III.B.5., III.B.7.–III.C.2.c.(ii), III.D.–D.2.b., III.D.3.b., III.E.–E.2.c., PART E, I.–I.D., I.D.3.–3.a.(ii), II.–II.A.4.b., II.A.4.b.(ii)–4.c., II.A.4.e.–A.8.b.(i), III.–III.B.4.n., IV.–IV.A.7.c.

TABLE 2—LIST OF COLORADO REVISIONS TO REG. 7 THAT THE EPA IS TAKING NO ACTION ON

Revised sections	Reason for "no action"
May 14, 2018 Submittal:	
XII.A.1., XII.A.1.c., XII.A.1.d.(ii), XII.A.3.–7., XII.B., XII.B.4.–5., XII.B.14., XII.B.22.–23., XII.C., XII.C.1.a., XII.C.1.e.(i)–(ii), XII.C.1.f.–(ii), XII.D., XII.D.1., XII.D.2.a.–(i), XII.D.2.a.(vi)–(vii), XII.E., XII.E.2.c., XII.F., and XII.F.4.	Superseded by the May 13, 2020 submittal.
XII.J.1	Provision to be acted on in a future rule-making.
XVIII.B.4[7]	State requested that this be a "state only" definition.[8]
May 8, 2019 Submittal:	
XII.J.1.j	Superseded by the May 13, 2020 submittal.
May 13, 2020 submittal:	
Part E, II.A.4.b.(i) and II.A.4.d.–(i)	Provisions not previously approved in the SIP.
I.D.–D.3.a.(i), I.D.3.b.–b.(i), I.D.3.b.(ii), I.D.3.b.(v), I.D.3.b.(vii), I.D.3.b.(ix), I.D.4.–I.E.1.a., I.E.2.–.c.(ii), I.E.2.c.(iv)–c.(viii), I.F.–1.d., I.F.1.g.–g.(xii), I.F.1.h.–F.2.a., I.F.2.c.–c.(vi), I.F.3.–3.a, I.F.3.c.–c.(i)(C), and I.J.1.	Provisions to be acted on in a future rule-making.

TABLE 3—CATEGORIES, FINAL ACTION, AND CORRESPONDING SECTIONS OF SUBMITTALS

Category	Final action	Location of RACT demonstration
Aerospace	Approval	Negative declaration. p. 6–3 of Colorado's Serious State Implementation Plan for the Denver Metro and North Front Range Ozone Nonattainment Area.[9]
General solvent use at major sources	Approval	pp. 619–620, 706, 2800, 2803 and Technical Support Document for Reasonably Available Control Technology for Major Sources (document number 56, p. 2134) of the May 13, 2020 submission.
Emissions from stationary internal combustion engines and flares at certain major sources.	Approval	pp. 619, 622, 724, 2800–2801, 2803 and Technical Support Document for Reasonably Available Control Technology for Major Sources (document number 56, p. 2134) of the May 13, 2020 submission.

IV. Incorporation by Reference

In this document, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of Colorado Reg. 7 pertaining to regulation of sources of VOC and NO_X emissions, except that we are not acting on the following submitted revisions: Reg. 7, Sections XII.J.1 from the May 14, 2018 submittal and Part D, Sections I.D., I.E., I.F. and I.J.1. from the May 13, 2020 submittal (as specified in Table 2

[7] Revised Section III.B.4.

[8] *See* March 1, 2021 email and attached letter from Colorado on "Revised Pneumatics SIP Revisions Justification" and May 3, 2021 email from Leah Martland, Colorado Air Pollution Control Division (contained within the docket). The definition for "enhanced response" is in reference to the State Only pneumatics "find and fix" program and thus not applicable to SIP provisions.

[9] *See* Colorado's March 22, 2021 submittal, document set 16 (in the docket for this action).

above). The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 8 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by the EPA for inclusion in the State implementation plan, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[10]

V. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, 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); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

We proposed to approve state rules as meeting the CAA standard for RACT, which the EPA has defined as the lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility. We also proposed to determine that this rule, if finalized, would not have disproportionately high or adverse human health or environmental effects on minority or low-income populations as described in Executive Order 12898. As to the state rules we are approving in this action, we received no comments concerning disproportionate impacts. In addition, as explained above, EPA is not taking final action on certain portions of the RACT SIP submittals that we proposed to approve. We will take final action on those portions of the RACT SIP submittal at a later date. Accordingly, we will be further evaluating compliance with this executive order at a later date, when we take final action on those remaining portions of the RACT SIP submittals.

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 4, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

Dated: October 28, 2021.

Debra H. Thomas,

Acting Regional Administrator, Region 8.

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 G—Colorado

■ 2. In § 52.320, the table in paragraph (c) is amended by removing the center heading ''5 CCR 1001–09, Regulation Number 7, Control of Ozone Via Ozone Precursors and Hydrocarbons via Oil and Gas Emissions, (Emissions of Volatile Organic Compounds and Nitrogen Oxides)'' and its subsequent entries and adding the following five center headings and their subsequent entries in its place:

■ a. ''5 CCR 1001–09, Regulation Number 7, Control of Ozone Via Ozone Precursors and Hydrocarbons via Oil and Gas Emissions, (Emissions of Volatile Organic Compounds and Nitrogen Oxides), Part A, Applicability and General Provisions'';

■ b. ''5 CCR 1001–09, Regulation Number 7, Control of Ozone Via Ozone Precursors and Hydrocarbons via Oil and Gas Emissions, (Emissions of Volatile Organic Compounds and Nitrogen Oxides), Part B, Storage, Transfer, and Disposal of Volatile Organic Compounds and Petroleum Liquids and Petroleum Processing and Refining'';

■ c. ''5 CCR 1001–09, Regulation Number 7, Control of Ozone Via Ozone

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

Precursors and Hydrocarbons via Oil and Gas Emissions, (Emissions of Volatile Organic Compounds and Nitrogen Oxides), Part C, Surface Coating, Solvents, Asphalt, Graphic Arts and Printing, and Pharmaceuticals'';

■ d. ''5 CCR 1001–09, Regulation Number 7, Control of Ozone Via Ozone Precursors and Hydrocarbons via Oil and Gas Emissions, (Emissions of Volatile Organic Compounds and Nitrogen Oxides), Part D, Oil and Natural Gas Operations''; and

■ e. ''5 CCR 1001–09, Regulation Number 7, Control of Ozone Via Ozone Precursors and Hydrocarbons via Oil and Gas Emissions, (Emissions of Volatile Organic Compounds and Nitrogen Oxides), Part E, Combustion Equipment and Major Source RACT''.

The additions read as follows:

§ 52.320 Identification of plan.

* * * * *

(c) * * *

Title	State effective date	EPA effective date	Final rule citation/date	Comments
* *	*	*	*	* *
5 CCR 1001–09, Regulation Number 7, Control of Ozone Via Ozone Precursors and Hydrocarbons via Oil and Gas Emissions, (Emissions of Volatile Organic Compounds and Nitrogen Oxides), Part A, Applicability and General Provisions				
I. Applicability	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 8/5/11 except for I.A.1.b, I.B.1.b, I.B.2.b, and I.B.2.d; nonsubstantive changes approved 7/3/2018, 2/24/2021, and 11/5/2021.
II. General Provisions	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 8/5/2011 except for II.A.12, II.C.1, and the repeal of previously approved II.D; nonsubstantive changes to II.D approved 7/3/2018; nonsubstantive changes approved 2/24/2021 and 11/5/2021.
5 CCR 1001–09, Regulation Number 7, Control of Ozone Via Ozone Precursors and Hydrocarbons via Oil and Gas Emissions, (Emissions of Volatile Organic Compounds and Nitrogen Oxides), Part B, Storage, Transfer, and Disposal of Volatile Organic Compounds and Petroleum Liquids and Petroleum Processing and Refining				
I. General Requirements for Storage and Transfer of Volatile Organic Compounds.	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 8/5/2011. nonsubstantive changes approved 2/24/2021 and 11/5/2021.
II. Storage of Highly Volatile Organic Compounds	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 8/5/2011. nonsubstantive changes approved 11/5/2021.
III. Disposal of Volatile Organic Compounds	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approvals 8/5/2011 and 2/24/2021; nonsubstantive changes approved 11/5/2021.
IV. Storage and Transfer of Petroleum Liquid	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 8/5/2011; nonsubstantive changes to approved 7/3/2018 and 2/24/201. Substantive changes approved 11/5/2021.
V. Crude Oil	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 8/5/2011; nonsubstantive approved 7/3/2018, 2/24/2021, and 11/5/2021.
VI. Petroleum Processing and Refining	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 8/5/2011; nonsubstantive changes approved 7/3/2018, 2/24/2021, and 11/5/2021.
VII. Control of Volatile Organic Compound Leaks from Vapor Collection Systems and Vapor Control Systems Located at Gasoline Terminals, Gasoline Bulk Plants, and Gasoline Dispensing Facilities.	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 8/5/2011; nonsubstantive changes approved 2/24/2021, substantive changes made to VII.-VII.B.2.b approved 11/5/2021.
Appendix B Criteria for Control of Vapors from Gasoline Transfer to Storage Tanks.	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous approval 5/30/95. Substantive changes approved 11/5/2021
Appendix C Criteria for Control of Vapors from Gasoline Transfer at Bulk Plants.	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous approval 3/13/81. Nonsubstantive changes approved 11/5/2021.
5 CCR 1001–09, Regulation Number 7, Control of Ozone Via Ozone Precursors and Hydrocarbons via Oil and Gas Emissions, (Emissions of Volatile Organic Compounds and Nitrogen Oxides), Part C, Surface Coating, Solvents, Asphalt, Graphic Arts and Printing, and Pharmaceuticals				
I. Surface Coating Operations	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 8/5/2011; nonsubstantive changes approved 7/3/2018; substantive changes approved 2/24/2021, nonsubstantive changes approved 11/5/2021.
II. Solvent Use	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 8/5/2011; substantive changes approved 2/24/2021 and 11/5/2021.
III. Use of Cutback Asphalt	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 8/5/2011; nonsubstantive changes approved 2/24/2021 and 11/5/2021.
IV. Graphic Arts and Printing	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 8/5/2011. Substantive changes made in 7/3/2018 rulemaking. IBR correction approved 2/24/2021. Nonsubstantive changes approved 11/5/2021.
V. Pharmaceutical Synthesis	2/14/2020	12/6/2021	[insert **Federal Register** citation], [insert date of publication in the FEDERAL REGISTER].	Previous SIP approval 8/5/2011;, nonsubstantive changes approved 2/24/2021 and [insert date of publication in the **Federal Register**].
Appendix D Minimum Cooling Capacities for Refrigerated Freeboard Chillers on Vapor Degreasers.	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 5/30/95. Nonsubstantive changes approved 11/5/2021.
Appendix E Emissions Limit Conversion Procedure	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 5/30/95. Nonsubstantive changes approved 11/5/2021.
5 CCR 1001–09, Regulation Number 7, Control of Ozone Via Ozone Precursors and Hydrocarbons via Oil and Gas Emissions, (Emissions of Volatile Organic Compounds and Nitrogen Oxides), Part D, Oil and Natural Gas Operations				

Title	State effective date	EPA effective date	Final rule citation/date	Comments
I. Volatile Organic Compound Emissions from Oil and Gas Operations.	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 2/13/2008. Substantive changes to Section XII; state-only provisions excluded, approved 7/3/2018. Substantive changes approved 11/5/2021 except no action on Sections I.D., I.E., I.F. and I.J.1.
II. Statewide Controls for Oil and Gas Operations	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Substantive changes to II.C., II.C.1., II.C.1.b.(ii)-(B), and II.F approved 11/5/2021.
III. Natural Gas-Actuated Pneumatic Controllers Associated with Oil and Gas Operations.	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Substantive changes to III.-III.B.3., III.B.5., III.B.7.-III.C.2.c.(ii), III.D.–III.D.2.b., III.D.3.b., and III.E.–III.E.2.c. approved 11/5/2021.
5 CCR 1001–09, Regulation Number 7, Control of Ozone Via Ozone Precursors and Hydrocarbons via Oil and Gas Emissions, (Emissions of Volatile Organic Compounds and Nitrogen Oxides), Part E, Combustion Equipment and Major Source RACT				
I. Control of Emissions from Engines	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approval 8/19/2005 and 12/31/2012; nonsubstantive changes to sections XVI.A.–C. 7/3/2018; substantive changes approved 2/24/2021, except sections XVI.D.4.b.(i) and XVI.D.4.d. Section XVII.E.3.a. from the Regional Haze SIP approved in SIP. Previous SIP approval 12/31/2012; nonsubstantive changes approved 2/24/2021 and 11/5/2021.
II. Control of Emissions from Stationary and Portable Engines and Other Combustion Equipment in the 8-Hour Ozone Control Area.	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	Previous SIP approvals 8/19/2005 and 12/31/2012; nonsubstantive changes to approved7/3/2018; substantive changes approved 2/24/2021 except sections XVI.D.4.b.(i) and XVI.D.4.d. Substantive changes approved 11/5/2021.
III. Control of Emissions from Specific Major Sources of VOC and/or NOx in the 8-Hour Ozone Control Area.	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	New section approved in SIP 2/24/2021. Substantive changes approved 11/5/2021.
IV. Control of Emissions from Breweries in the 8-hour Ozone Control Area.	2/14/2020	12/6/2021	[insert **Federal Register** citation], 11/5/2021.	New section approved in SIP 2/24/2021. Nonsubstantive changes approved 11/5/2021.
* *	*	*	*	* *

* * * * *

[FR Doc. 2021–24026 Filed 11–4–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2021–0017; FRL–9091–02–R3]

Air Plan Approval; Maryland; Baltimore Area Base Year Inventory for the 2015 Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision formally submitted by the State of Maryland. This revision consists of the base year inventory for the Baltimore, Maryland marginal nonattainment area (Baltimore Area) for the 2015 ozone national ambient air quality standards (NAAQS). This action is being taken under the Clean Air Act (CAA).

DATES: This final rule is effective on December 6, 2021.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2021–0017. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

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

SUPPLEMENTARY INFORMATION: On July 30, 2020, the Maryland Department of the Environment (MDE), on behalf of the State of Maryland, submitted a revision to the Maryland SIP entitled, ''2015 8-Hour Ozone NAAQS (0.070 ppm) Marginal Area State Implementation Plan for the Baltimore, MD Nonattainment Area, SIP #20–08.'' This SIP revision, referred to in this rule action as the ''Baltimore base year inventory SIP,'' addresses the base year inventory requirement for the 2015 ozone NAAQS.

I. Background

On October 1, 2015, EPA strengthened the 8-hour ozone NAAQS, lowering the level of the NAAQS from 0.075 parts per million (ppm) to 0.070 ppm. 80 FR 65292 (October 26, 2015). Effective August 3, 2018, EPA designated the Baltimore Area, consisting of Anne Arundel, Baltimore, Carroll, Harford, and Howard Counties and the City of Baltimore, all in Maryland, as marginal nonattainment for the 2015 ozone NAAQS. 83 FR 25776 (June 4, 2018). CAA section 182(a)(1) requires ozone nonattainment areas classified as marginal or above to submit a comprehensive, accurate, current inventory of actual emissions from all emissions sources in the nonattainment area, known as a ''base year inventory.'' The Baltimore base year inventory SIP addresses a base year inventory requirement for the Baltimore Area.

II. Summary of SIP Revision and EPA Analysis

A. EPA's Evaluation of the Baltimore Base Year Inventory SIP

EPA's review of Maryland's base year inventory SIP for the Baltimore Area indicates that it meets the base year inventory requirements for the 2015 ozone NAAQS. As required by 40 CFR 51.1315(a), MDE selected 2017 for the base year inventory, which is consistent with the baseline year for the reasonable further progress (RFP) plan because it is the year of the most recent triennial inventory. MDE included actual ozone season emissions, pursuant to 40 CFR 51.1315(c).

EPA prepared a Technical Support Document (TSD) in support of this rule. In that TSD, EPA reviewed the results, procedures, and methodologies for the SIP base year, and found them to be acceptable and developed in accordance with EPA's technical guidance. The TSD is available online at *http://www.regulations.gov,* Docket ID No. EPA–R03–OAR–2021–0017.

B. Base Year Inventory Requirements

In EPA's December 6, 2018 (83 FR 62998) rule, ''Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area State Implementation Plan Requirements,'' known as the ''SIP Requirements Rule,'' EPA set out nonattainment area requirements for the 2015 ozone NAAQS. The SIP Requirements Rule established base year inventory requirement, which were codified at 40 CFR 51.1315. As required by 40 CFR 51.1315(a), each 2015 ozone nonattainment area to submit a base year inventory within 2 years of designation, *i.e.,* by no later than August 3, 2020.

Also, 40 CFR 51.1315(a) requires that the inventory year be selected consistent with the baseline year for the RFP plan as required by 40 CFR 51.1310(b), which states that the baseline emissions inventory shall be the emissions inventory for the most recent calendar year for which a complete triennial inventory is required to be submitted to EPA under the provisions of subpart A of 40 CFR part 51, Air Emissions Reporting Requirements, 40 CFR 51.1–50. The most recent triennial inventory year conducted for the National Emissions Inventory (NEI) pursuant to the Air Emissions Reporting Requirements (AERR) rule is 2017. 73 FR 76539 (December 17, 2008). Maryland selected 2017 as their baseline emissions inventory year for RFP. This selection comports with EPA's implementation regulations for the 2015 ozone NAAQS because 2017 is the inventory year. 40 CFR 51.1310(b).[1] Further, 40 CFR 51.1315(c) requires emissions values included in the base year inventory to be actual ozone season day emissions as defined by 40 CFR 51.1300(q), which sates: Ozone season day emissions means an average day's emissions for a typical ozone season work weekday. The state shall select, subject to EPA approval, the particular month(s) in the ozone season and the day(s) in the work week to be represented, considering the conditions assumed in the development of RFP plans and/or emissions budgets for transportation conformity.

C. Baltimore Base Year Inventory SIP

The Baltimore base year inventory SIP contains an explanation of MDE's 2017 base year emissions inventory for Baltimore (2017 Baltimore BYE) for stationary, non-point, non-road, and on-road anthropogenic sources, as well as biogenic sources, in the Baltimore Area. MDE estimated anthropogenic emissions for volatile organic compound (VOC), nitrogen oxide (NO_X), and carbon monoxide (CO) for a typical ozone season workweek day.

MDE developed the 2017 Baltimore BYE with the following source categories of anthropogenic emissions sources: Point, quasi-point, non-point, non-road, on-road, biogenic, and commercial marine vessels, airport, and railroad emissions sources (MAR). Appendix A of the Baltimore base year inventory SIP, 2017 Base Year SIP Emissions Inventory Methodologies (Appendix A), sets out the methodologies MDE used to develop its base year inventory.[2]

EPA's review of Maryland's base year inventory SIP for the Baltimore Area indicates that it meets the base year inventory requirements for the 2015 ozone NAAQS. Other specific requirements of MDE's July 30, 2020 submittal and the rationale for EPA's proposed action, including further information on each source category, are explained in the notice of proposed rulemaking (NPRM) and will not be restated here. No public comments were received on the NPRM.

III. Final Action

EPA's review of this material indicates the Baltimore base year inventory SIP meets the base year inventory requirement for the 2015 ozone NAAQS for the Baltimore Area. Therefore, EPA is approving the Baltimore base year inventory SIP, which was submitted on July 30, 2020.

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, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

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

[1] On January 29, 2021, the Court of Appeals for the D.C. Circuit issued its decision regarding multiple challenges to EPA's implementation rule for the 2015 ozone NAAQS which included, among other things, upholding this provision allowing states to use an alternative baseline year for RFP. *Sierra Club* v. *EPA,* No. 15–1465 (D.C. Cir.) (mandate not yet issued). The other provisions of EPA's ozone implantation rule at issue in the case are not relevant for this rule.

[2] The Appendix A—2017 Base Year SIP Emission Inventory Methodologies, submitted with the 2015 8-Hour Ozone NAAQS Marginal Area State Implementation Plan for the Baltimore, MD Nonattainment Area is included in the docket for this rule available online at *https://www.regulations.gov,* Docket ID: EPA–R03–OAR–2021–0017.

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this final rule, approving Maryland's base year inventory SIP for the 2015 ozone NAAQS, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

Dated: October 19, 2021.

Diana Esher,

Acting Regional Administrator, Region III.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart V—Maryland

■ 2. In § 52.1070, the table in paragraph (e) is amended by adding an entry for ''Baltimore Area Base Year Inventory for the 2015 Ozone National Ambient Air Quality Standards'' at the end of the table to read as follows:

§ 52.1070 Identification of plan.

* * * * *

(e) * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
* *	*	*	*	* *
Baltimore Area Base Year Inventory for the 2015 Ozone National Ambient Air Quality Standards.	Baltimore Area in Maryland.	7/30/20	11/5/21, [insert **Federal Register** citation].	The Baltimore Area consists of Anne Arundel, Baltimore, Carroll, Harford, and Howard Counties and the City of Baltimore.

[FR Doc. 2021–23975 Filed 11–4–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket No. 17–59; DA 21–1240; FRS 54669]

Consumer and Governmental Affairs Bureau Announces Interim Usage Charges for the Reassigned Numbers Database

AGENCY: Federal Communications Commission.

ACTION: Interim action.

SUMMARY: The Consumer and Governmental Affairs Bureau (Bureau) of the Federal Communications Commission (FCC or Commission) announces the initial interim usage charges for subscriptions to the Reassigned Numbers Database beginning November 1, 2021. Callers and caller agents will be able to use the Database to determine whether a telephone number has been reassigned from the consumer they intend to reach, thus allowing them to avoid calling consumers with reassigned numbers who may not wish to receive their call.

DATES: The initial interim usage charges for subscriptions to the Reassigned Numbers Database were applicable beginning November 1, 2021.

FOR FURTHER INFORMATION CONTACT: Karen Schroeder, Associate Division Chief, Consumer Policy Division, Consumer and Governmental Affairs Bureau at (202) 418–0654 or via email at *Karen.Schroeder@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Public Notice, DA 21–1240, CG Docket No. 17–59, released on October 1, 2021. The full text of this document is available online at *https://www.fcc.gov/document/fcc-announces-interim-usage-charges-reassigned-numbers-data.* To request this document in accessible formats for people with disabilities (*e.g.,* Braille, large print, electronic files, audio format) or to request reasonable accommodations (*e.g.,* accessible format documents, sign language interpreters, CART), send an email to *fcc504@fcc.gov* or call the FCC's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice).

Paperwork Reduction Act of 1995 Analysis

This document does not contain any new or modified information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. It, therefore, does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Synopsis

1. In this document, the Consumer and Governmental Affairs Bureau (Bureau) announces the initial interim usage charges for subscriptions to the Reassigned Numbers Database (Database or RND). After a successful beta test, the Database was available for full use on November 1, 2021.

2. *Subscription Tiers and Rates.* The RND will offer six subscription tiers: Extra Small, Small, Medium, Large, Extra Large, and Jumbo, as summarized in the table below and further detailed in the Appendix. Those wishing to use the RND may sign up for a one-month subscription, a three-month subscription, or a six-month subscription. The RND Administrator (Administrator) expects to offer an annual subscription option in the future, as well.

Tiers	1-Month Subscription Queries	1 -Month Subscription Usage Charge	3-Month Subscription Queries	3-Month Subscription Usage Charge	6-Month Subscription Queries	6-Month Subscription Usage Charge
Tier 1: Extra Small	1,000	$ 10	3,000	$ 30	6,000	$ 60
Tier 2: Small	10,000	$ 75	30,000	$ 225	60,000	$ 450
Tier 3: Medium	500,000	$ 2,500	1,500,000	$ 7,500	3,000,000	$ 15,000
Tier 4: Large	2,000,000	$ 5,000	6,000,000	$ 15,000	12,000,000	$ 30,000
Tier 5: Extra Large	10,000,000	$ 20,000	30,000,000	$ 60,000	60,000,000	$ 120,000
Tier 6: Jumbo	30,000,000	$ 35,100	90,000,000	$ 105,300	180,000,000	$ 210,600

Table Showing Examples of RND Interim Usage Charges

3. The interim tiers and usage charges are the same regardless of whether the subscriber is a caller or a caller agent. Caller agents may register for a tier based on the aggregate number of queries needed for all of their clients, potentially allowing caller agents to register for a higher tier (and thus pay a lower charge per query) than their individual clients would use on their own.

4. *Other Usage Charge Features.* Under the interim usage charge model, if a subscriber exhausts its queries before the end of the subscription term, it has three options:

- *Buy a new subscription.* After using all the queries in the original subscription, the caller may purchase a new subscription. The new subscription would begin a new term (one-month, three-month, or six-month, depending on the option the subscriber selects).
- *Upgrade to a higher tier.* The subscriber has the option to pay the difference between the original tier and a new, higher tier, to increase the number of queries available, while keeping the original subscription term the same.
- *Top off the subscription.* The subscriber has the option to pay 10% of the usage charge of the subscription to receive 10% more queries, while keeping the original subscription term the same.

5. *Basis for the Interim Usage Charges.* The interim usage charges are based on the Administrator's recommendation guidance, consistent with the *Advanced Methods to Target and Eliminate Unlawful Robocalls,* Second Report and Order, 84 FR 11226, March 26, 2019, 33 FCC Rcd 12024, 12025 (2018); the contract's Performance Work Statement; and a recommendation from the North American Numbering Council. In addition, the Administrator obtained some information from the volume of queries entered by users of the Database during the RND beta test.

6. *Adjustments to the Interim Usage Charges.* The Commission required the Administrator to provide monthly analyses of the impacts of the interim usage charge structure. The Administrator may adjust the usage charges, including the number of tiers, the number of queries in the tiers, and the charge for each tier, on a monthly basis with approval of the Commission. The Bureau welcomes feedback via telephone or email to the Administrator. Contact information for the Administrator is located on the support page of the RND website, found at *https://www.reassigned.us/support.*

7. The Administrator will post notice of changes to the interim usage charges on the RND website (*https://wwww.reassigned.us*) two weeks before they go into effect. Registered subscribers will receive notice of changes to the interim usage charges before their subscription ends as part of the RND renewal notification process.

8. The Bureau anticipates that the Commission may commence a proceeding to establish a more permanent rate structure that would go into effect no sooner than January 1, 2023. The Bureau acknowledges that this is a unique scenario. Given the lack of data available, despite prior attempts to obtain it from commenters, and the inability to accurately predict the correct usage charges over an extended period without making the Database available to users, combined with the commitment to setting a usage charge that will encourage Database usage, the Bureau has determined that the best course forward is to set these interim usage charges and adjust them as the Administrator collects data throughout the first year of the Database's operation. Users of the Database have the ability to give continuous feedback to the Administrator as the Bureau works through setting the usage charge structure for the RND.

9. *Ex Parte Rules.* The Bureau encourages users of the Database to provide feedback on usage charges directly to the Administrator. These communications are not subject to *ex parte* restrictions. However, if interested parties desire to make presentations to bureau staff on matters concerning the Database and usage charges, this proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentations within two business days after the presentations (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule § 1.1206(b). In proceedings governed by rule § 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the

electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in the proceeding should familiarize themselves with the Commission's *ex parte* rules. The Administrator is exempt from the *ex parte* requirements. This exemption is necessary to allow the Administrator to engage in the frequent and close communications with Commission staff needed to exercise their administrative functions efficiently.

10. *People with Disabilities.* To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice).

11. *Additional Information.* For further information regarding the Public Notice, please contact Karen Schroeder, Associate Division Chief, Consumer Policy Division, Consumer and Governmental Affairs Bureau at (202) 418–0654 or via email at *Karen.Schroeder@fcc.gov.*

12. *Applicability Date.* Good cause exists for making the interim usage charges in this document applicable upon publication of this document in the **Federal Register**, except as to those who have actual notice of the interim usage charges and choose to purchase a subscription for the Database prior to publication.

13. The Database was available for use on November 1, 2021. Providing a 30-day period after **Federal Register** publication before the interim usage charges in this document become applicable isn't necessary because the Database is now available. There is good cause to make these usage charges applicable upon **Federal Register** publication for the Administrator to collect subscription payments. Additionally, these interim usage charges became effective immediately for Database users who have actual notice of the charges and have purchased a subscription to the Database prior to **Federal Register** publication. For these reasons, and because participation in the RND is voluntary, there is good cause, pursuant to section 553(d)(3) of the Administrative Procedure Act, to make the interim usage charges in this document applicable upon publication in the **Federal Register**, except as to those parties with actual notice.

Federal Communications Commission.

Robert Garza,

Legal Advisor, Consumer and Governmental Affairs Bureau, Federal Communications Commission.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix—RND Subscription Tiers and Usage Charges

Tiers	Cost/Query	% of Discount from Base	1-Month Subscription Queries	1-Month Subscription Usage Charge	3-Month Subscription Queries	3-Month Subscription Usage Charge	6-Month Subscription Queries	6-Month Subscription Usage Charge
Tier 1: Extra Small	$0.01	NA	1,000	$ 10	3,000	$ 30	6,000	$ 60
Tier 2: Small	$0.0075	25%	10,000	$ 75	30,000	$ 225	60,000	$ 450
Tier 3: Medium	$0.005	50%	500,000	$ 2,500	1,500,000	$ 7,500	3,000,000	$ 15,000
Tier 4: Large	$0.0025	75%	2,000,000	$ 5,000	6,000,000	$ 15,000	12,000,000	$ 30,000
Tier 5: Extra Large	$0.00200	80%	10,000,000	$ 20,000	30,000,000	$ 60,000	60,000,000	$ 120,000
Tier 6: Jumbo	$0.00117	88%	30,000,000	$ 35,100	90,000,000	$ 105,300	180,000,000	$ 210,600

[FR Doc. 2021–23855 Filed 11–4–21; 8:45 am]

BILLING CODE 6712–01–P

GENERAL SERVICES ADMINISTRATION

48 CFR Part 517

[GSAR–TA–2022–01; Docket No. GSA–GSAR–2021–0025; Sequence No. 1]

General Services Administration Acquisition Regulation; Personal Identity Verification Requirements Clarification; Correction

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Final rule; correction.

SUMMARY: The General Services Administration (GSA) is issuing this final rule to amend the General Services Administration Acquisition Regulation (GSAR) to make a needed technical amendment. This technical amendment is to remove regulatory text regarding contract administration for exercising options that was incorrectly addressed in previous rulemaking.

DATES: Effective: November 5, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Vernita L. Misidor, Procurement Analyst, at 202–357–9681 or email at *gsarpolicy@gsa.gov* for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite GSAR–TA–2022–01.

SUPPLEMENTARY INFORMATION: This final rule amends the General Services Administration Acquisition Regulation (GSAR) to make needed technical amendments. Following internal procurement management reviews, GSA identified the need to improve certain credentialing administration processes for contractors. As a result, GSA amended the GSAR through GSAR Case 2020–G525 to clarify the personal identity verification requirements (86 FR 28499). Under this rule, language regarding contract administration for options was also removed from regulation as the language speaks to internal operating procedures. However, the amendatory instructions for the options language was noted incorrectly in the rule. This technical amendment corrects that mistake and removes section 517.207.

List of Subjects in 48 CFR Part 517

Government procurement.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Governmentwide Policy, General Services Administration.

Therefore, GSA amends 48 CFR part 517 by making the following correcting amendment:

PART 517—SPECIAL CONTRACTING METHODS

■ 1. The authority citation for 48 CFR part 517 continues to read as follows:

Authority: 40 U.S.C. 121(c).

Section 517.207 [Removed]

■ 2. Remove section 517.207.

[FR Doc. 2021–23938 Filed 11–4–21; 8:45 am]

BILLING CODE 6820–61–P

GENERAL SERVICES ADMINISTRATION

48 CFR Part 552

[GSAR Case 2017–G506; Docket No. GSA–GSAR 2021–0016; Sequence No. 1]

RIN 3090–AJ90

General Services Administration Acquisition Regulation (GSAR); Clause and Provision Designation Corrections; Correction

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Final rule; correction.

SUMMARY: On October 6, 2021, GSA published a final rule to amend the General Services Administration Acquisition Regulation (GSAR) to correct clause and provision designation and prescription errors, correct deviations and alternate identification issues, and to make other updates to the GSAR related to identification and incorporation of GSAR provisions and clauses. This document makes editorial corrections in that rule.

DATES: Effective November 5, 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas O'Linn, Procurement Analyst, at 202–445–0390 or *gsarpolicy@gsa.gov,* for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite GSAR Case 2017–G506.

SUPPLEMENTARY INFORMATION: In FR Doc. 2021–20541 appearing on pages 55516–55525 in the issue of October 6, 2021, make the following corrections:

552.227–71 [Corrected]

■ 1. On page 55523, in the third column, in section 552.227–71, correct the phrase ''As prescribed in 527.409–70(b)'' to read ''As prescribed in 527.409(b)''.

■ 2. On page 55524, in the first column, amend instruction 78 by removing the text ''552.111(a)'' and adding ''532.111(a)'' in its place.

■ 3. On page 55524, in the first column, amend instruction 79 by removing the text ''552.111(b)'' and adding ''532.111(b)'' in its place.

■ 4. On page 55524, in the third column, in section 552.241–71, correct the phrase ''As prescribed in 541.570(b)'' to read ''As prescribed in 541.501(b)''.

■ 5. On page 55525, in the first column, in section 555.252–5, correct the provision heading ''Authorized Deviations in Provisions (DATE)(Deviation FAR 52.252–5)'' to read ''Authorized Deviations in Provisions (NOV 2021)(Deviation FAR 52.252–5)'' in its place.

■ 6. On page 55525, in the first column, in section 555.252–6, correct the clause heading ''Authorized Deviations in Clauses (DATE)(Deviation FAR 52.252–6)'' to read ''Authorized Deviations in Clauses (NOV 2021)(Deviation FAR 52.252–6)'' in its place.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy, General Services Administration.

[FR Doc. 2021–23940 Filed 11–4–21; 8:45 am]

BILLING CODE 6820–61–P

Proposed Rules

Federal Register
Vol. 86, No. 212
Friday, November 5, 2021

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

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2021–0134]

RIN 3150–AK67

List of Approved Spent Fuel Storage Casks: TN Americas LLC, TN–32 Dry Storage Cask, Certificate of Compliance No. 1021, Renewal of Initial Certificate and Amendment No. 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its spent fuel regulations by revising the TN Americas LLC, TN–32 Dry Storage Cask listing within the ''List of approved spent fuel storage casks'' to renew, for an additional 40 years, the initial certificate and Amendment No. 1 of Certificate of Compliance No. 1021. The renewal of the initial certificate and Amendment No. 1 revises the certificate of compliance's conditions and technical specifications to address aging management activities related to the structures, systems, and components of the dry storage system to ensure that these will maintain their intended functions during the period of extended storage operations. The scope of the Certificate of Compliance No. 1021 renewal includes spent fuel storage cask models TN–32, TN–32A, and TN–32B.

DATES: Submit comments by December 6, 2021. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit your comments, identified by Docket ID NRC–2021–0134, at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

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

FOR FURTHER INFORMATION CONTACT: Christian Jacobs, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–6825, email: *Christian.Jacobs@nrc.gov* and Caylee Kenny, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–7150, email: *Caylee.Kenny@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0134 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0134. Address questions about NRC dockets to Dawn Forder, telephone: 301–415–3407, email: *Dawn.Forder@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2021–0134 in your comment submission. The NRC requests that you submit comments through the Federal rulemaking website at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

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

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

II. Rulemaking Procedure

Because the NRC considers this action to be noncontroversial, the NRC is publishing this proposed rule concurrently with a direct final rule in the Rules and Regulations section of this issue of the **Federal Register**. The direct final rule will become effective on January 19, 2022. However, if the NRC receives any significant adverse comments by December 6, 2021, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments in a subsequent final rule. Absent significant

modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule.

For a more detailed discussion of the proposed rule changes and associated analyses, see the direct final rule published in the Rules and Regulations section of this issue of the **Federal Register**.

III. Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended, requires that ''[t]he Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the Nuclear Waste Policy Act states, in part, that ''[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule that added a new subpart K in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L in 10 CFR part 72 entitled ''Approval of Spent Fuel Storage Casks,'' which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on March 20, 2000 (65 FR 14790), that approved the TN–32 Dry Storage Cask System design and added it to the list of NRC-approved cask designs in § 72.214 as Certificate of Compliance No. 1021.

IV. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885). The NRC requests comment on the proposed rule with respect to clarity and effectiveness of the language used.

V. Availability of Documents

The documents identified in the following table are available to interested persons, as indicated.

Document	ADAMS Accession No.
TN Americas LLC Renewal Application for the TN–32 Dry Storage Cask Certificate of Compliance No. 1021, dated March 5, 2020.	ML20065J427
TN Americas LLC Response to Request for Additional Information for the Application for the Renewal of Certificate of Compliance No. 1021, dated November 11, 2020.	ML20316A030
Supplemental Response to Request for Additional Information for the TN Americas LLC Application for Renewal of the TN–32 Dry Storage Cask, Certificate of Compliance No. 1021, dated February 5, 2021.	ML21036A237
Supplemental Response to Request for Additional Information for the TN Americas LLC Application for Renewal of the TN–32 Dry Storage Cask, Certificate of Compliance No. 1021, dated March 17, 2021.	ML21076A040
User Need Memorandum for Rulemaking for Certificate of Compliance Renewal, Initial Issue (Amendment Number 0), Amendment Number 1 to TN–32 Dry Storage Cask, dated July 29, 2021.	ML21127A079
Preliminary Safety Evaluation Report for the TN–32 Dry Storage Cask Certificate of Compliance Renewal	ML21127A082
Proposed Certificate of Compliance No. 1021, Renewed Initial Certificate	ML21127A080
Proposed Technical Specifications, Appendix A, Certificate of Compliance No. 1021, Renewed Initial Certificate	ML21127A083
Proposed Certificate of Compliance No. 1021, Renewed Amendment No. 1	ML21127A081
Proposed Technical Specifications, Appendix A, Certificate of Compliance No. 1021, Renewed Amendment No. 1	ML21127A084

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2021–0134.

Dated: October 25, 2021.

For the Nuclear Regulatory Commission.

Daniel H. Dorman,

Executive Director for Operations.

[FR Doc. 2021–24211 Filed 11–4–21; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0662; Project Identifier MCAI–2021–00031–E]

RIN 2120–AA64

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM).

SUMMARY: The FAA is revising a notice of proposed rulemaking (NPRM) that applied to certain Rolls-Royce Deutschland Ltd & Co KG (RRD) Trent 1000 model turbofan engines. This action revises the NPRM by reopening the comment period because the NPRM was placed in incorrect Docket No. FAA–2021–0637 instead of Docket No. FAA–2021–0662. The FAA is proposing this airworthiness directive (AD) to address the unsafe condition on these products. Since commenters experienced difficulties in commenting on the NPRM, the FAA is requesting comments on this SNPRM.

DATES: The FAA must receive comments on this SNPRM by December 20, 2021.

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

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

For service information identified in this SNPRM, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; phone: +44 (0)1332 242424; fax: +44 (0)1332 249936; website: *https://www.rolls-royce.com/contact-us.aspx*. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0662; 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 SNPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Kevin Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7088; fax: (781) 238–7199; email: *kevin.m.clark@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0662; Project Identifier MCAI–2021–00031–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this SNPRM 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 SNPRM, 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 SNPRM. Submissions containing CBI should be sent to Kevin Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued an NPRM to amend 14 CFR part 39 by adding an AD that would apply to RRD Trent 1000–AE3, Trent 1000–CE3, Trent 1000–D3, Trent 1000–G3, Trent 1000–H3, Trent 1000–J3, Trent 1000–K3, Trent 1000–L3, Trent 1000–M3, Trent 1000–N3, Trent 1000–P3, Trent 1000–Q3, and Trent 1000–R3 model turbofan engines. The NPRM published in the **Federal Register** on August 13, 2021 (86 FR 44655). The NPRM was prompted by reports of high levels of wear on the seal fins on a small number of certain high-pressure turbine triple seals. In the NPRM, the FAA proposed to require manual deactivation of the modulated air system (MAS) control valves.

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2021–0009, dated January 8, 2021 (referred to after this as ''the MCAI''), to address the unsafe condition on these products. The MCAI states:

> The Modulated Air System (MAS) optimises cooling air, extracted from the compressor, where full flow is not required at cruise conditions. It is only active during cruise. Recently, occurrences have been reported of finding high levels of wear on the seal fins on a small number of high pressure turbine triple seals, Part Number FW34485. The effect on the secondary air system was conservatively assessed due to the resultant increased turbine cooling air leakage, which changes the cooling flow around the intermediate pressure (IP) turbine disc.
>
> This condition, if not corrected, could lead to temperature increase at the IP turbine disc rim when the MAS is active, possibly resulting in IP turbine disc failure and high energy debris release, with consequent damage to, and reduced control of, the aeroplane.
>
> To address this potential unsafe condition, Rolls-Royce has issued the NMSB, providing instructions to manually 'lock-out' (deactivate) the MAS control valves.
>
> For the reason described above, this [EASA] AD requires to deactivate the MAS control valves. This [EASA] AD also specifies that the Master Minimum Equipment List (MMEL) item for 'MAS inoperative', which has a limit of 120 days, does not apply when the system is manually deactivated.

You may obtain further information by examining the MCAI in the AD

docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0662.

Actions Since the NPRM Was Issued

Since the FAA issued the NPRM, the FAA determined the NPRM was inadvertently placed in incorrect Docket No. FAA–2021–0637 instead of Docket No. FAA–2021–0662. The FAA received information that the public had difficulty commenting on the NPRM.

Comments

The FAA received comments on the NPRM from two commenters. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Revise the Unsafe Condition

The Boeing Company (Boeing) requested the FAA revise paragraph (e), Unsafe Condition, of the NPRM to accurately reflect the effect of the AD on the unsafe condition. Boeing suggested revising paragraph (e) to state ''This AD was prompted by reports of high levels of wear on the seal fins on a small number of certain high-pressure turbine (HPT) triple seals. This condition, if not addressed, could lead to temperature increase at the Intermediate Pressure (IP) turbine disk rim when the Modulated Air System (MAS) is active during cruise, possibly resulting in failure of the IP turbine disk, loss of engine thrust control, and loss of the airplane. The FAA is issuing this AD to restore cooling airflow to the IP turbine disk rim during cruise by deactivating MAS.'' Boeing reasoned that the AD action to deactivate the MAS does not prevent wear on the HPT triple seal fins. Deactivating the MAS restores cooling airflow to the intermediate-pressure turbine (IPT) disk rim during cruise.

The FAA updated paragraph (e) of this proposed AD by stating, ''This AD was prompted by reports of high levels of wear on the seal fins on a small number of certain high-pressure turbine triple seals. The FAA is issuing this AD to ensure cooling airflow restoration to the intermediate-pressure turbine (IPT) disk rim during cruise by deactivating the modulated air system (MAS). The unsafe condition, if not addressed, could result in a temperature increase at the IPT disk rim, when the MAS is active during cruise, resulting in failure of the IPT disk, loss of engine thrust control, and loss of the airplane.''

Request To Correct Part Number Reference

Rolls-Royce notified the FAA that the preamble of the NPRM incorrectly identifies the HPT triple seal part number (P/N) as FW3448, whereas the correct identification is FW34485.

The FAA agrees and has revised the Background section of this proposed AD by correcting the reference to the HPT triple seal P/N from FW3448 to FW34485.

FAA's Determination

This product has been approved by EASA and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Community, EASA has notified the FAA of the unsafe condition described in the MCAI and service information. The FAA is proposing this AD because the agency evaluated all the relevant information provided by EASA and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design. The public had difficulty commenting on the NPRM. As a result, the FAA has determined that it is necessary to reopen the comment period to provide opportunity for the public to comment on this SNPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Rolls-Royce Alert Non-Modification Service Bulletin Trent 1000 75–AK642, Initial Issue, dated November 30, 2020. The service information specifies procedures for deactivating the MAS control valves. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Proposed Requirements in This SNPRM

This proposed AD would require manual deactivation of the MAS control valves. Manual deactivation of the MAS control valves changes the engine to an approved configuration that will produce engine indicating and crew alerting system (EICAS) status messages that do not indicate inoperative (failed) equipment. Consequently, when these messages are displayed, the operator's existing FAA-approved minimum equipment list (MEL) instructions and limitations, including the 120-day operation limitation, do not apply.

Interim Action

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

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 4 engines installed on 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
Deactivate the MAS control valves	2 work-hours × $85 per hour = $170	$0	$170	$680

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Rolls-Royce Deutschland Ltd & Co KG (Type Certificate previously held by Rolls-Royce plc): Docket No. FAA–2021–0662; Project Identifier MCAI–2021–00031–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 20, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce Deutschland Ltd & Co KG (RRD) (Type Certificate previously held by Rolls-Royce plc) Trent 1000–AE3, Trent 1000–CE3, Trent 1000–D3, Trent 1000–G3, Trent 1000–H3, Trent 1000–J3, Trent 1000–K3, Trent 1000–L3, Trent 1000–M3, Trent 1000–N3, Trent 1000–P3, Trent 1000–Q3, and Trent 1000–R3 model turbofan engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7250, Turbine Section.

(e) Unsafe Condition

This AD was prompted by reports of high levels of wear on the seal fins on a small number of certain high-pressure turbine triple seals. The FAA is issuing this AD to ensure cooling airflow restoration to the intermediate-pressure turbine (IPT) disk rim during cruise by deactivating the modulated air system (MAS). The unsafe condition, if not addressed, could result in a temperature increase at the IPT disk rim when the MAS is active during cruise, resulting in failure of the IPT disk, loss of engine thrust control, and loss of the airplane.

(f) Compliance

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

(g) Required Actions

Within the compliance time specified in figure 1 to paragraph (g) of this AD, deactivate the MAS control valves using the Accomplishment Instructions, paragraphs 3.A.(6) and 3.A.(7), of Rolls-Royce Alert Non-Modification Service Bulletin Trent 1000 75–AK642, Initial Issue, dated November 30, 2020.

Note 1 to paragraph (g): Deactivation of the MAS control valves on an engine required by paragraph (g) of this AD changes the engine to an approved configuration that will produce engine indicating and crew alerting system (EICAS) status messages ''ENG MAS VALVE L/R'' and ''ENG MAS SYS TEST L/R.'' Since MAS is purposely disabled after compliance with paragraph (g) of this AD, these status messages do not indicate inoperative (failed) equipment and, consequently, the operator's existing FAA-approved minimum equipment list (MEL) instructions and limitations, including the 120-day operation limitation, do not apply.

Note 2 to paragraph (g): Deactivation of the MAS control valves on an engine as required by paragraph (g) of this AD does not produce the EICAS status message ''ENG MAS VALVE SENSOR L/R.'' Consequently, when this EICAS message displays, it remains indicative of inoperative equipment, even if the MAS has been disabled as required by paragraph (g) of this AD. As a result, the corresponding MEL instructions and limitations apply whenever the EICAS status message ''ENG MAS VALVE SENSOR L/R'' is displayed.

Figure 1 to paragraph (g) – Compliance time

MAS deactivation option	Compliance time, whichever occurs later after the effective date of this AD, A or B
A	Within 50 engine flight cycles (FCs) since new
B	Within 30 days or 100 FCs, whichever occurs first

(h) Alternative Methods of Compliance (AMOCs)

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

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

(i) Related Information

(1) For more information about this AD, contact Kevin Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7088; fax: (781) 238–7199; email: *kevin.m.clark@faa.gov*.

(2) Refer to European Union Aviation Safety Agency (EASA) AD 2021–0009, dated January 8, 2021, for more information. You may examine the EASA AD in the AD docket at *https://www.regulations.gov* by searching for and locating it in Docket No. FAA–2021–0662.

(3) For service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; phone: +44 (0)1332 242424; fax: +44 (0)1332 249936; website: *https://www.rolls-royce.com/contact-us.aspx*. You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

Issued on October 29, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24056 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0949; Project Identifier AD–2021–00115–E]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all General Electric Company (GE) CF6–80C2A1, CF6–80C2A2, CF6–80C2A3, CF6–80C2A5, CF6–80C2A5F, and CF6–80C2A8 model turbofan engines with an installed left-hand rear mount link assembly, part number (P/N) 1846M23G01. This proposed AD was prompted by the manufacturer reducing the life limit for the affected left-hand rear mount link assembly. This proposed AD would require revising the Airworthiness Limitations section (ALS) of the GE CF6–80C2 Engine Manual, GEK92451, and the operator's existing approved continuous airworthiness maintenance program (CAMP). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 20, 2021.

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

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

For service information identified in this NPRM, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215, phone: (513) 552–3272; email: *aviation.fleetsupport@ae.ge.com*; website: *www.ge.com*. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0949; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Scott Stevenson, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7132; fax: (781) 238–7199; email: *Scott.M.Stevenson@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0949; Project Identifier AD–2021–00115–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Scott Stevenson, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA received a report from the manufacturer reducing the life limit for the affected left-hand rear mount link assembly. The left-hand rear mount link assembly was redesigned and certified in 1999, and the FAA subsequently issued AD 2000–12–08 (65 FR 39536, June 27, 2000), mandating the replacement of the affected left-hand rear mount link assembly with a part eligible for installation. Later, analysis from the aircraft manufacturer of stress loads in their extended service goal mission profile revealed loads during the take-off phase that were not included at certification. These additional loads result in a reduced life limit on the left-hand rear mount link assembly. This condition, if not addressed, could result in separation of the engine from the airplane, and loss of the airplane.

FAA's Determination

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

Related Service Information

The FAA reviewed GE CF6–80C2 Temporary Revision (TR) 05–0276, dated July 13, 2021 (GE TR 05–0276), and GE CF6–80C2 TR 05–0277, dated July 9, 2021 (GE TR 05–0277). GE TR 05–0276 and GE TR 05–277 provide the new life limit to be updated into the ALS, for the affected left-hand rear mount link assembly, in the GE CF6–80C2 Engine Manual, GEK92451.

Proposed AD Requirements in This NPRM

This proposed AD would require revising the ALS of the GE CF6–80C Engine Manual, GEK92451, as applicable to each affected engine model, and the operator's existing approved CAMP to incorporate a reduced life limit for the affected left-hand rear mount link assembly, P/N 1846M23G01.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 220

engines installed on 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
Revise ALS of Engine Manual and the operator's existing approved CAMP.	2 work-hour × $85 per hour = $170	$0	$170	$37,400

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

General Electric Company: Docket No. FAA–2021–0949; Project Identifier AD–2021–00115–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 20, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to General Electric Company (GE) CF6–80C2A1, CF6–80C2A2, CF6–80C2A3, CF6–80C2A5, CF6–80C2A5F, and CF6–80C2A8 model turbofan engines with an installed left-hand rear mount link assembly, part number (P/N) 1846M23G01.

(d) Subject

Joint Aircraft System Component (JASC) Code 7120, Engine Mount Section.

(e) Unsafe Condition

This AD was prompted by a report from the manufacturer on an updated analysis of stress loads during take-off, which revealed a stress increase with take-off phase loads that were not included at certification. The FAA is issuing this AD to lower the life limit of the left-hand rear mount link assembly and prevent the failure of the engine mount system. The unsafe condition, if not addressed, could result in separation of the engine from the airplane, and loss of the airplane.

(f) Compliance

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

(g) Required Actions

Within 180 days after the effective date of this AD, revise the Airworthiness Limitations section of the GE CF6–80C2 Engine Manual, GEK92451, and the operator's existing approved continuous airworthiness maintenance program, by reducing the life limit of the left-hand rear mount link assembly, P/N 1846M23G01, from 50,000 flight cycles (FCs) to 23,800 FCs.

(h) Alternative Methods of Compliance (AMOCs)

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

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

(i) Related Information

(1) For more information about this AD, contact Scott Stevenson, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7132; fax: (781) 238–7199; email: *Scott.M.Stevenson@faa.gov*.

(2) For service information identified in this AD, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: *aviation.fleetsupport@ae.ge.com*; website: *www.ge.com*. You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

Issued on October 27, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24071 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0958; Project Identifier 2019–CE–010–AD]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace Corporation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Gulfstream Aerospace Corporation (Gulfstream) Model GV and GV–SP airplanes. This proposed AD results from corrosion of the horizontal stabilizer lower bonded skin assemblies. This proposed AD would require inspecting the horizontal stabilizer lower skin and associated bonded doublers and bonded stringers, repairing the area susceptible to corrosion, and incorporating revisions to the airworthiness limitations section (ALS) in the existing aircraft maintenance manual (AMM). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 20, 2021.

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

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

For service information identified in this NPRM, contact Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, GA 31402; phone: (800) 810–4853; fax: (912) 965–3520; email: *pubs@gulfstream.com*; website: *https://www.gulfstream.com/en/customer-support/*. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0958; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Ronald Wissing, Aviation Safety Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (404) 474–5552; fax: (404) 474–5606; email: *ronald.wissing@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0958; Project Identifier 2019–CE–010–AD'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Ronald Wissing, Aviation Safety Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, GA 30337. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Gulfstream notified the FAA of bond line corrosion on Model GV and GV–SP airplanes, which causes disbonding between the horizontal stabilizer lower skin and associated bonded doublers and bonded stringers. Gulfstream determined that the existing visual inspection in the AMM does not reliably detect bond line corrosion, and they added a repetitive non-destructive testing (NDT) inspection to detect the damage. Gulfstream added the revised inspections to the ALS of the AMM. This condition, if not addressed, could compromise the structural integrity of the horizontal stabilizer and lead to loss of control of the airplane.

FAA's Determination

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed Gulfstream G500–5000 Customer Bulletin No. 190, Revision B; Gulfstream G550 Customer Bulletin No. 190, Revision B; and Gulfstream GV Customer Bulletin No. 228, Revision B; all dated October 31, 2019. For the applicable marketing designation specified on each document, the customer bulletins specify procedures for inspecting the horizontal stabilizer lower bonded skin.

The FAA also reviewed Gulfstream V Maintenance Manual, Airworthiness Limitations, Section 05–10–10, dated February 28, 2020; Gulfstream G500–5000 Maintenance Manual, Airworthiness Limitations, Section 05–10–10, dated March 15, 2021; and Gulfstream G550 Maintenance Manual, Airworthiness Limitations, Section 05–10–10, dated March 15, 2021. For the applicable marketing designation specified on each document, the service information contains inspection intervals for nondestructive testing of the lower horizontal stabilizer skins and provides the specific reference for the inspection procedures.

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

Other Related Service Information

The FAA also reviewed the following service documents related to this NPRM:

- Gulfstream Service Letter Document No. GSL505510019, Revision E, dated September 3, 2021, which contains procedures for applying on-wing corrosion inhibiting compound to the horizontal stabilizer.
- Gulfstream Service Letter Document No. GSL505510020, Revision C, dated March 12, 2020, which contains procedures for applying corrosion inhibiting compound to the horizontal stabilizer.
- Gulfstream V Nondestructive Testing Procedures Manual Chapter 05–00–00, 1. Horizontal Stabilizer Lower Skin Resonance C-Scan—NDT Procedure.

Proposed AD Requirements in This NPRM

This proposed AD would require inspecting the horizontal stabilizer lower skin and associated bonded doublers and bonded stringers, repairing the area susceptible to corrosion, and incorporating revisions to the ALS of the existing AMM.

Differences Between This Proposed AD and the Service Information

The differences between Gulfstream G500–5000 Customer Bulletin No. 190, Revision B; Gulfstream G550 Customer Bulletin No. 190, Revision B; and Gulfstream V Customer Bulletin No. 228, Revision B; all dated October 31, 2019, and this proposed AD are listed below.

- The service bulletins exclude certain serial-numbered airplanes inspected by Gulfstream, but this proposed AD would apply to all Model GV and GV–SP airplanes.
- The service bulletins include an optional horizontal stabilizer lower skin resonance A-Scan NDT inspection (referred to in the Customer Bulletin as ''Part I Inspection'') for critical areas of the horizontal stabilizer bonded lower skin assemblies, but this proposed AD would not require the Part I Inspection.
- The service bulletins allow the horizontal stabilizer lower skin resonance C-Scan NDT inspection (referred to in the Customer Bulletin as a ''Part II Inspection'') and application of corrosion inhibiting compound to be repeated indefinitely every 48 months. This proposed AD would only allow the Part II inspection to be performed one time and, within 48 months after the inspection, would require approved repairs.
- The customer bulletins contain actions labeled ''Required for Compliance'' (RC), and the language in the customer bulletin and in paragraph (j)(4) of this proposed AD indicate that operators must comply with all actions labeled RC for compliance with this AD. However, this AD does not require all of the steps in the customer bulletins that are labeled as RC. Operators only need to comply with the RC steps required by paragraph (i) of this AD.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect up to 694 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
Resonance C-Scan NDT (Part II) inspection and CIC application.	80 work-hours × $85 per hour = $6,800.	Not applicable ...	$6,800	$2,196,400 (for 323 airplanes).
AMM revision	1 work-hour × $85 per hour = $85.	Not applicable ...	85	$58,990 (for 694 airplanes).

The extent of corrosion found during the proposed inspection may vary significantly from airplane to airplane. The FAA has no way of determining the number of airplanes that might need repair or the cost to repair each airplane.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Gulfstream Aerospace Corporation: Docket No. FAA–2021–0958; Project Identifier 2019–CE–010–AD.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 20, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Gulfstream Aerospace Corporation Model GV and GV–SP airplanes, all serial numbers, certificated in any category.

Note 1 to paragraph (c): Model GV–SP airplanes are also referred to by the marketing designations G500, G550, and G500–5000.

(d) Subject

Joint Aircraft System Component (JASC) Code 5510, Horizontal Stabilizer Structure.

(e) Unsafe Condition

This AD results from corrosion of the horizontal stabilizer lower bonded skin assemblies. The FAA is issuing this AD to detect and correct bond line corrosion, which if not addressed, could result in compromise of the structural integrity of the horizontal stabilizer and lead to loss of control of the airplane.

(f) Compliance

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

(g) Incorporation of Airworthiness Limitations (ALS) Revisions

Within 30 days after the effective date of this AD, incorporate into your existing maintenance or inspection program the ALS revision specified in paragraph (g)(1), (2), or (3) of this AD for your applicable airplane designation.

(1) *For Model GV airplanes:* Section F and Table 12: Horizontal Stabilizer Inspection Table in section 05–10–10, Airworthiness Limitations, of the Gulfstream V Maintenance Manual, dated February 28, 2020;

(2) *For Model GV–SP (G500 and G500–5000) airplanes:* Section F and Table 12: Horizontal Stabilizer Inspection Table in section 05–10–10, Airworthiness Limitations, of the Gulfstream G500–5000 Maintenance Manual, dated March 15, 2021; or

(3) *For Model GV–SP (G550) airplanes:* Section F and Table 12: Horizontal Stabilizer Inspection Table in section 05–10–10, Airworthiness Limitations, of the Gulfstream G550 Maintenance Manual, dated March 15, 2021.

(h) Applicable Customer Bulletins

The customer bulletins specified in paragraphs (h)(1) through (3) of this AD contain procedures for compliance with the actions required by paragraph (i) of this AD for your applicable airplane designation.

(1) Gulfstream GV Customer Bulletin No. 228, Revision B, dated October 31, 2019;

(2) Gulfstream G500–5000 Customer Bulletin No. 190, Revision B, dated October 31, 2019; or

(3) Gulfstream G550 Customer Bulletin No. 190, Revision B, dated October 31, 2019.

(i) Inspection

For Model GV airplanes, all serial numbers, and Model GV–SP airplanes, serial numbers 5001 through 5158, where more than 132 months have elapsed since the original certificate of airworthiness issue date (often referred to as entry into service date), as of the effective date of this AD: Within 12 months after the effective date of this AD, perform the horizontal stabilizer lower skin resonance C-Scan inspection (Part II inspection) for bond line corrosion and apply corrosion inhibiting compound (CIC) by following steps 6.2.a. through 6.2.e. and 6.3.a. of appendix A of the applicable customer bulletin listed in paragraph (h) of this AD.

Note 2 to the introductory text of paragraph (i): The inspections listed in the applicable ALS revision in paragraph (g) of this AD must also be accomplished at the same time you perform the Part II inspection.

(1) Within 48 months after applying CIC, repair the area using a method approved as specified in paragraph (j)(3) of this AD.

(2) If there is bond line corrosion that exceeds the allowable damage limit, before further flight, repair the area using a method approved as specified in paragraph (j)(3) of this AD.

(j) Alternative Methods of Compliance (AMOCs)

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

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

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

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the following provisions apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

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

(k) Related Information

(1) For more information about this AD, contact Ronald Wissing, Aviation Safety Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (404) 474–5552; fax: (404) 474–5606; email: *ronald.wissing@faa.gov*.

(2) For service information identified in this AD, contact Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, GA 31402; phone: (800) 810–4853; fax: (912) 965–3520; email: *pubs@gulfstream.com*; website: *https://www.gulfstream.com/en/customer-support/*. You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued on October 28, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24082 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–13–P

NATIONAL LABOR RELATIONS BOARD

29 CFR Part 102

RIN 3142–AA20

Use of Videoconference Technology To Conduct Unfair Labor Practice and Representation Case Proceedings

AGENCY: National Labor Relations Board.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The National Labor Relations Board (''NLRB,'' ''Agency,'' or ''Board'') seeks public input on the use of videoconference technology to conduct, in whole or in part, all aspects and phases of unfair labor practice and representation case hearings and on potential amendments to its procedural rules regarding the use of videoconference technology. The Board's current Rules and Regulations provide for the taking of a single witness's testimony via video in an unfair labor practice proceeding upon a showing of good cause based on compelling circumstances. During the COVID–19 pandemic, the Board, through adjudication, sanctioned entirely remote hearings in both unfair labor practice and representation cases. The Board has no intention to

permanently replace in-person hearings with virtual hearings. To the contrary, once conditions permit, the Board intends to resume conducting in-person hearings. But, based on the Board's experience during the pandemic, the Board is considering whether to retain virtual hearings as an option for future use. Accordingly, the Board solicits responses to targeted questions regarding, among other things, stakeholders' experiences with remote hearings during the pandemic; the benefits and/or drawbacks of using videoconference technology to conduct remote hearings; and the need for, and content of, potential amendments to the Board's rules regarding use of videoconference technology to conduct remote hearings.

DATES: Comments must be received on or before January 4, 2022. 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 *http://www.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 mailed 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.

Only comments submitted through *http://www.regulations.gov,* hand delivered, or mailed will be accepted; ex parte communications received by the Board will be made part of the rulemaking record and will be treated as comments only insofar as appropriate. Comments will be available for public inspection at *http://www.regulations.gov*.

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 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.

The Board requests that comments include full citations or internet links to any authority relied upon.

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:

I. Background

A. Remote Testimony in Board Proceedings Pre-Pandemic

The NLRB is an independent federal agency established in 1935 to promote workplace democracy and, in the words of former President Franklin Delano Roosevelt, ''to foster the development of the employee contract on a sound and equitable basis.'' For more than 85 years, the NLRB has been at the forefront of the effort to promote and protect the rights and obligations of employees, unions, and employers under the National Labor Relations Act (''the Act''). The NLRB achieves these objectives by carrying out two principal statutory functions: (1) Conducting representation elections among employees to determine their wishes regarding union representation (''representation cases''); and (2) investigating and prosecuting alleged unfair labor practices by employers and unions (''unfair labor practice cases'').

Under the Act, the Board, when necessary, must provide fair and impartial evidentiary hearings to adjudicate issues raised in unfair labor practice and representation cases. *See* 29 U.S.C. 160(b) (requiring a notice of hearing upon issuance of an unfair labor practice complaint); *id.* 159(c)(1) (requiring ''an appropriate hearing'' if a question concerning representation exists); *accord* 5 U.S.C. 554 (due process standards for administrative adjudication under the Administrative Procedure Act). Administrative law judges presiding over unfair labor practice cases, and hearing officers presiding over representation cases, have historically conducted hearings in person.

With the advent of sophisticated, accessible, and high-quality videoconference technology in the broadband era, the Agency has taken several steps to integrate videoconferencing into representation and unfair labor practice proceedings. In 2008, the Board approved a two-year pilot program to test the use of video testimony in representation cases in limited circumstances involving remote witnesses, parties, or hearing officers, and/or multiple locations. *See* Pilot Video Testimony Program in Representation Cases, OM Memo 08–20 (Jan. 8, 2008). Midway through the pilot program, the Associate General Counsel for Operations reported that ''few offices [had] utilized video testimony to obtain evidence'' in representation cases; however, ''[t]hose Regions with video testimony experience state that its use can be very helpful in controlled situations,'' and ''offices experienced no problems when taking video testimony.'' Pilot Video Testimony Program in Representation Cases Mid-Term Report, OM Memo 09–43 (CH), at 1 (Mar. 16, 2009). Moreover, the Associate General Counsel observed that the use of video technology to obtain evidence during regional investigations of unfair labor practice charges could be appropriate in limited circumstances, subject to regional personnel consulting with the Division of Operations-Management. *Id.*

In 2011, the Agency made the pilot program permanent. *See* Video Testimony in Representation and Unfair Labor Practice Casehandling, OM Memo 11–42 (CH), at 1 (Mar. 30, 2011). In the same 2011 memo, the Acting General Counsel expanded the earlier pilot program by authorizing regional attorneys to use video technology to introduce witness testimony in

contested unfair labor practice hearings, ''where good cause is shown, compelling circumstances exist and appropriate safeguards are in place.'' *Id.* at 2–3 & n.3 (listing factors to consider before granting a request for video testimony). Consistent with this policy, in 2015, the Board, with judicial approval, affirmed the judge's finding that the use of videoconferencing technology to obtain hearing testimony from a witness living abroad did not deny the respondent due process. *EF Int'l Lang. Sch., Inc.,* 363 NLRB No. 20, slip op. at 1 n.1, 3–5 (2015), *enforced,* 673 F. App'x 1, 3–4 (DC Cir. 2017). The Board rejected arguments that videoconference technology was insufficient to allow the judge to make credibility determinations, noting that ''the videoconferencing technology used enabled [the judge's] observation of the witness at all material times.'' *Id.,* slip op. at 1 n.1; *see also MPE, Inc.,* 09–CA–084228, 2015 WL 400660, at *1 (Jan. 29, 2015) (unpublished order) (finding that judge erred in refusing to allow video testimony from otherwise unavailable witness).

In 2017, the Board amended its Rules and Regulations to set standards for the taking of a single witness's testimony in an unfair labor practice case via video transmission in an otherwise in-person hearing. The rule allows contemporaneous, remote witness testimony ''[u]pon a showing of good cause based on compelling circumstances, and under appropriate safeguards.'' 29 CFR 102.35(c). It delineates the process required for a party to apply to obtain testimony by videoconference, 102.35(c)(1), and offers a non-exhaustive list of appropriate safeguards to ''ensure that the Administrative Law Judge has the ability to assess the witness's credibility and that the parties have a meaningful opportunity to examine and cross-examine the witness,'' 102.35(c)(2). The Board's rules pertaining to representation hearings do not contain a corresponding provision, and, as of March 2020, representation hearings continue to be governed by the standards set forth in OM Memos 08–20, 09–43 (CH), and 11–42 (CH).

B. Remote Hearings During the COVID–19 Pandemic

1. The COVID–19 pandemic, and related federal, state, and local guidance and orders, pushed the Board to quickly expand its videoconferencing capabilities and pivot to widespread use of remote hearings in both representation and unfair labor practice cases. In April 2020, at the beginning of the pandemic, Regional Directors exercised their delegated authority under Section 3(b) of the Act to schedule representation case hearings through videoconference or teleconference. *See* COVID–19 Operational Status Update (Apr. 17, 2020), *https://www.nlrb.gov/news-outreach/news-story/covid-19-operational-status-update.* On May 11, 2020, the Board issued its decision in *Morrison Healthcare,* 369 NLRB No. 76 (2020), approving the use of videoconference technology to hear witness testimony at an all-remote hearing. The Board held that videoconference hearings in representation cases would be appropriate ''on a showing of good cause based on compelling circumstances and under appropriate safeguards.'' *Id.,* slip op. at 1. The Board further found that the COVID–19 pandemic constituted ''compelling circumstances'' warranting a remote preelection hearing in the case under review. *Id.,* slip op. at 2. As for appropriate safeguards, the Board left ''it to the hearing officer in the first instance to impose appropriate safeguards, informed but not controlled by those listed in Sec[tion] 102.35(c)(2),'' which, as stated, governs remote testimony in unfair labor practice proceedings. *Id.,* slip op. at 1 n.2. In contrast, the Board held that a telephonic representation case hearing would be appropriate ''only where compelling circumstances exist and no witness testimony is involved,'' though the Board left open the possibility that parties could agree to a telephonic hearing. *Id.,* slip op. at 1, 2 & n.4.

In April 2020, the Board's Division of Judges ordered that no in-person unfair labor practice hearings would be scheduled through May 31, 2020. On May 15, 2020, the Division of Judges announced that it would begin holding virtual hearings on unfair labor practice complaints effective June 1, 2020. On August 13, 2020, the Board issued its decision in *William Beaumont Hospital,* 370 NLRB No. 9 (2020), resolving its first challenge to a judge's decision to hold a hearing remotely in an unfair labor practice case. Guided by *Morrison,* the Board found ''nothing in the Board's Rules, or the Act, that precludes a judge or Regional Director from ordering a videoconference hearing in an unfair labor practice case, on a showing of good cause based on compelling circumstances and under appropriate safeguards.'' *Id.,* slip op. at 1. Nor does the Fifth Amendment's Due Process Clause per se preclude conducting administrative hearings via videoconference. *Id.,* slip op. at 1 n.2. The Board further found that the judge did not abuse his discretion in finding the COVID–19 pandemic was a compelling circumstance justifying a remote hearing, nor in imposing appropriate safeguards informed but not controlled by those listed in Section 102.35(c)(2). *Id.,* slip op. at 1–2. The Board emphasized that the respondent could raise any non-speculative due process concerns with the trial judge in the first instance, or later on exceptions to the Board under Section 102.46 of the Board's Rules and Regulations. *Id.,* slip op. at 2; *see also XPO Cartage, Inc.,* 370 NLRB No. 10 (2020) (denying respondent's special appeal from judge's order directing remote hearing); *Boeing Co.,* 10–CA–204795, 2020 WL 5204848 (Aug. 31, 2020) (unpublished order) (same).

In a May 2021 decision, the Board acknowledged the ''evolving state of the pandemic,'' including more widespread vaccinations and some jurisdictions returning to in-person hearings and trials. *Michael Cetta, Inc.,* 02–CA–142626, 2021 WL 1966555, at *2 (May 14, 2021) (unpublished order). Nevertheless, the Board did not find ''that conditions have improved so much . . . as to *mandate* a return to in-person hearings''; thus, it found, the judge did ''not abuse[ ] his discretion in relying on the ongoing pandemic as a compelling circumstance necessitating a remote hearing'' in that case. *Id.* (original emphasis).

2. During the early months of the pandemic, the Agency built an infrastructure to ensure that hearings could continue safely. The Agency acquired additional licenses and equipment necessary to conduct hearings remotely using videoconferencing technology, adding Zoom for Government to its software inventory as its primary remote hearing platform. The General Counsel and Division of Judges trained the Agency's Regional staff and administrative law judges on using the technology in a trial setting. The Division of Judges established guidance and best practices for its remote hearings, including methods for sharing exhibits and *Jencks* statements,[1] managing witnesses and participants, and handling sequestration orders. To allow for public access, the Agency determined that the Regional Offices, upon request, would issue non-participant observers a link to any hearing they wished to observe.

For unfair labor practice cases, the Agency also set up its ''Courtroom Deputy'' program, designed to assist

[1] *See Jencks* v. *United States,* 353 U.S. 657, 672 (1957).

judges and parties in remote hearings. Under that program, at the judge's request, an Agency employee trained in the Zoom for Government platform is assigned to cases scheduled for hearing. That individual attends the pretrial conference, conducts practice sessions with the parties, admits parties, witnesses, and attendees to the hearing, troubleshoots technological issues, shares exhibits via the platform's share screen function, handles the waiting room and breakout rooms, and otherwise assists the judge in ensuring that the hearing runs as smoothly as possible. The Agency screens and recuses the Courtroom Deputy from working on the case in any other capacity than as Courtroom Deputy. In *Michael Cetta, Inc.,* the Board rejected a challenge to the Courtroom Deputy program. 2021 WL 1966555, at *2.

Beginning with the Board's shift to remote hearings in Spring 2020 and through the end of Fiscal Year 2021, the Agency has conducted 207 unfair labor practice hearings and 487 representation case hearings via the Zoom for Government videoconferencing platform.

C. Remote Hearings and Trials at Other Federal Agencies and in the Federal Courts

The NLRB is not the only federal agency that has used or is using videoconference technology in its hearings before and during the pandemic. Prior to the pandemic, some federal agencies conducted remote hearings, in whole or in part, by telephone or videoconference.[2] Since at least 2011, the Administrative Conference of the United States (ACUS) has analyzed the use of remote hearing technology in federal administrative adjudication and issued guidance and best practices for federal agencies.[3] Like the NLRB, other federal agencies transitioned to remote hearings on a wider scale in response to the pandemic and the need to comply with health and safety protocols.[4]

As for the federal courts, they, like the NLRB, have long provided for remote testimony of a single witness in an otherwise in-person hearing. Rule 43(a) of the Federal Rules of Civil Procedure states that ''[f]or good cause in compelling circumstances and with appropriate safeguards, the court may permit testimony in open court by contemporaneous transmission from a different location.'' The comments to that rule, however, emphasize ''[t]he importance of presenting live testimony in court.'' Nevertheless, the pandemic also forced the federal courts to transition to remote proceedings. In March 2020, ''the Judicial Conference of the United States [ ] temporarily approved the use of video and teleconferencing for certain criminal proceedings and access via teleconferencing for civil proceedings during the COVID–19 national emergency.'' [5] Federal courts have even conducted remote civil jury trials.[6] The Judicial Conference has also permitted judges to authorize the use of teleconferencing to provide the public and media access to court proceedings.[7] Although some jurisdictions have returned to in-person proceedings in limited circumstances, the federal courts have not fully returned to pre-pandemic operations.[8]

II. Information Requested

The Board expects that in-person hearings will again be the norm once they can be held safely. Nevertheless, given the Board's largely successful experience with remote hearings during the pandemic, the Agency is evaluating what role, if any, videoconferencing should play in its hearings going forward and is considering whether to amend its representation and unfair labor practice rules to incorporate further use of videoconference technology in the future.

Your responses to the following questions will help the Board evaluate its options and develop a more informed notice of proposed rulemaking if issued. The questions are not all-inclusive, and any supplemental information is welcome. Comments are not required to address every question, but, in responding, please identify the question you are responding to and explain the reasons for your answer.

The Board is seeking public comment on the following questions:

1. What role should videoconference technology play in unfair labor practice and representation case hearings after pandemic restrictions end? Should it remain available as an option for the parties to conduct a fully remote hearing, a partially remote hearing, and/or an in-person hearing with remote testimony only by specifically designated witnesses?

2. Assuming the Board retains videoconference hearings as an option, what should the standard be for ordering one? Should it be at the discretion of the judge or Regional Director, or should there be a higher standard?

3. Should the agreement of the judge or Regional Director and all parties be required? If all parties do not consent, what would be the appropriate next steps to resolve the matter? Similarly, if all parties want a videoconference hearing, but the judge or Regional Director does not agree, what should be the appropriate next steps to resolve the matter?

4. Does the Board's use of videoconferencing present any technological or other barriers to participation in Board proceedings? If so, how might the Board attempt to mitigate those potential barriers?

5. How might the Board best accommodate the needs of videoconference hearing participants who require the services of an interpreter or translator?

6. In what ways could the NLRB improve its use or conduct of

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[2] *See* Admin. Conf. of the U.S., Recommendation 2011–4, *Agency Use of Video Hearings: Best Practices and Possibilities for Expansion,* 76 FR 48789, 48795–96 (Aug. 9, 2011), *available at https://www.acus.gov/recommendation/agency-use-video-hearings-best-practices-and-possibilities-expansion.*

[3] *See, e.g., id.;* Admin. Conf. of the U.S., Recommendation 2014–7, *Best Practices for Using Video Teleconferencing for Hearings,* 79 FR 75114, 75119–20 (Dec. 17, 2014), *available at https://www.acus.gov/recommendation/best-practices-using-video-teleconferencing-hearings.*

[4] Admin. Conf. of the U.S., Recommendation 2021–4, *Virtual Hearings in Agency Adjudication,* 86 FR 36075, 36083–85 (July 8, 2021), *available at https://www.acus.gov/recommendation/virtual-hearings-agency-adjudication* (stating that use of virtual hearings in agency proceedings ''expanded dramatically during the COVID–19 pandemic''). ACUS compiled and continues to update a list of agency issuances related to the COVID–19 pandemic, including those pertaining to virtual hearings. *Coronavirus (COVID–19) and Adjudication, ACUS.gov, https://www.acus.gov/coronavirus-and-adjudication* (last updated Sept. 16, 2021).

[5] *Judiciary Authorizes Video/Audio Access During COVID–19 Pandemic, UsCourts.gov* (Mar. 31, 2020), *https://www.uscourts.gov/news/2020/03/31/judiciary-authorizes-videoaudio-access-during-covid-19-pandemic.*

[6] *As Pandemic Lingers, Courts Lean Into Virtual Technology, UsCourts.gov* (Feb. 18, 2021), *https://www.uscourts.gov/news/2021/02/18/pandemic-lingers-courts-lean-virtual-technology.*

[7] *Judiciary Provides Public, Media Access to Electronic Court Proceedings, UsCourts.gov* (Apr. 3, 2020), *https://www.uscourts.gov/news/2020/04/03/judiciary-provides-public-media-access-electronic-court-proceedings.*

[8] *As COVID–19 Cases Fall, Juries Get Back to Work, UsCourts.gov* (May 27, 2021), *https://www.uscourts.gov/news/2021/05/27/covid-19-cases-fall-juries-get-back-work.* The United States Courts' website maintains COVID–19 related information for each jurisdiction. *Court Orders and Updates During COVID–19 Pandemic, UsCourts.gov, https://www.uscourts.gov/about-federal-courts/court-website-links/court-orders-and-updates-during-covid19-pandemic* (last updated Sept. 30, 2021); *see also Federal Courts Respond to COVID–19: Live Map,* Bloomberg Law, *https://news.bloomberglaw.com/us-law-week/arguments-axed-access-limited-courts-respond-to-covid-19-map* (last updated Sept. 22, 2021).

videoconference hearings, including best practices derived from your experiences in the federal courts, state courts, or other federal agencies, which could inform how the Board develops a rule?

7. Please provide feedback on the Agency's ''Courtroom Deputy'' program that provides technical assistance to judges to allow them to focus on the legal elements of the hearing. Should the Agency retain the program? Would you have concerns about the Agency contracting with third parties, including court-reporting companies, to provide the same technical assistance? Either way, what are your suggestions for improving the services provided?

8. Did or do you feel adequately prepared to use the videoconference technology in a trial setting?

9. If further rulemaking is desirable, should the Board adopt separate rules for the use of videoconferencing in unfair labor practice and representation case hearings? If so, what are the differences between the two types of hearings that separate rules should reflect?

10. If further rulemaking is desirable, should the rule provide for a mechanism to appeal or for other Board review of a decision to hold a hearing via videoconference, or is the mechanism provided for in Sections 102.26 and 102.67(c) of the Board's Rules and Regulations adequate?

11. In your experience with NLRB videoconference hearings during the pandemic, have any technology limitations or problems in videoconference hearings interfered with the conduct of the hearings?

12. Has the use of videoconference technology affected the ability to successfully engage in mediation and/or settlement discussions?

13. Is there sufficient public access to Agency proceedings in a virtual environment?

14. Are there any privacy, confidentiality, or security concerns linked to public access to virtual Agency proceedings? If so, how should the Board address those concerns?

Dated: October 26, 2021.

Roxanne L. Rothschild,

Executive Secretary, National Labor Relations Board.

[FR Doc. 2021–23599 Filed 11–4–21; 8:45 am]

BILLING CODE 7545–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AR31

Readjustment Counseling Service Scholarship Program

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its regulations by adding new regulations that would govern scholarship programs to certain health care professionals. This rulemaking implements the mandates of the Commander John Scott Hannon Veterans Mental Health Care Improvement Act of 2019 by establishing the Readjustment Counseling Service Scholarship Program (RCSSP). The RCSSP provides educational assistance to individuals who pursue a graduate degree in psychology, social work, marriage and family therapy, or mental health counseling that meet the education requirements for appointment as a health care professional in one of those fields in VA Vet Centers.

DATES: Comments must be received on or before January 4, 2022.

ADDRESSES: Comments may be submitted through *www.Regulations.gov.* Comments should indicate that they are submitted in response to ''RIN 2900–AR31–Readjustment Counseling Service Scholarship Program.'' Comments received will be available at *regulations.gov* for public viewing, inspection, or copies.

FOR FURTHER INFORMATION CONTACT: Charles Flora, Social Science Specialist, Readjustment Counseling Services, 810 Vermont Ave. NW, Washington, DC 20420, (202) 461–6525. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: On October 17, 2020, § 502 of Public Law 116–171, the Commander John Scott Hannon Veterans Mental Health Care Improvement Act of 2019, amended 38 United States Code (U.S.C.) by establishing new §§ 7698 through 7699B and creating a new scholarship program known as the Readjustment Counseling Service Scholarship Program (RCSSP). The RCSSP would serve as an incentive to individuals who are pursuing a graduate degree in psychology, social work, marriage and family therapy, or mental health counseling to fill existing and future vacancies in Vet Centers.

Section 1712A(h)(1) of Title 38, U.S. Code defines a Vet Center as a facility which is operated by the Department for the provision of services under this section and which is situated apart from Department general health care facilities. The purpose of the Vet Center is to assist veterans in adjusting to civilian life or to provide readjustment to servicemembers for continued military service following participation in or support of operations in a combat theater or area of hostility; to assist family members of servicemembers when coping with such member's deployment; and to assist family members of veterans and servicemembers in aiding a veteran's or member's readjustment to civilian or continued military service following their participation in or support of operations in a combat theater or area of hostility, specifically as it relates to the veteran's or member's military experience.

The RCSSP would assist VA in filling vacancies in Vet Centers that are located in areas that are designated as medically underserved populations and in States with a per capita population of more than five percent veterans according to the National Center for Veterans Analysis and Statistics and the Bureau of the Census (42 U.S.C. 254b(b)(3)). This proposed rule would establish the requirements for the RCSSP in proposed 38 CFR 17.545 through 17.553.

Section 17.545 Purpose

Proposed § 17.545 would state the purpose of §§ 17.545 through 17.553, which is to establish the RCSSP as part of VA's Educational Assistance Program. We would also state that for purposes of the RCSSP, the term Vet Center has the meaning given in 38 U.S.C. 1712A(h). This section would be aligned with 38 U.S.C. 7698.

Section 17.547 Eligibility

Proposed § 17.547 would establish the eligibility criteria for participants of the RCSSP. These eligibility criteria are aligned with § 7699(a). We would state that an individual is eligible to participate in the RCSSP if that individual meets both of the following eligibility criteria: (1) The individual must be accepted for enrollment or be currently enrolled on a full-time basis in a program of study at an accredited educational institution, school, or training program leading to a terminal degree in psychology, social work, marriage and family therapy, or mental health counseling that would meet the education requirements for appointment to a position in one of those fields under 38 U.S.C. 7402(b) (§ 7402(b) of Title 38 U.S. Code provides the qualification requirements of appointees as VA health

care professionals); and (2) the individual must enter into an agreement with the Secretary under proposed § 17.551, which is described below.

Section 17.548 Scholarship Availability and Application Procedures

The Commander John Scott Hannon Veterans Mental Health Care Improvement Act of 2019 was silent on the availability of and application procedures for the RCSSP. We would, therefore, mirror the language of similar scholarship programs in proposed § 17.548 regarding the availability of and application procedures.

Proposed paragraph (a) would describe the availability for RCSSP scholarships. We would state that VA will make awards under the RCSSP only when VA determines it is necessary to assist in alleviating shortages or anticipated shortages of psychologists, social workers, marriage and family therapists, or mental health counseling professionals in Vet Centers. Additionally, we would state that VA's determination of the number of RCSSP scholarships to be awarded in a fiscal year is subject to the availability of appropriations. This language mirrors that in § 17.628.

Proposed paragraph (b) would state that each individual who seeks a RCSSP scholarship must submit an accurate and complete application, including a signed acceptance agreement. This language mirrors that in § 17.629.

We would state in proposed paragraph (c) that VA will notify applicants prior to acceptance in the RCSSP of the following information: A fair summary of the rights and liabilities of an individual whose application is approved by VA and whose acceptance agreement is consummated by VA; and full description of the terms and conditions that apply to participation in the RCSSP and service in VA. This language also mirrors § 17.629.

Section 17.549 Award Procedures

We would establish the award procedures for participants of the RCSSP in proposed § 17.549, which will include priority for selection, placement considerations, and amount of funding. Proposed paragraph (a) would be in alignment with 38 U.S.C. 7699(b) by establishing the two priorities for the selection of individuals to participate in the RCSSP. We would state in proposed paragraph (a)(1) that VA would give priority to an individual who agrees to be employed at Vet Centers that are located in communities that are designated as medically underserved populations under § 330(b)(3) of the Public Health Service Act (42 U.S.C. 254b(b)(3)) and Vet Centers that are located in States with a per capita population of more than five percent veterans according to the National Center for Veterans Analysis and Statistics and the Bureau of the Census. We would state in proposed paragraph (a)(2) that priority would also be given to veterans. In proposed paragraph (b) we would add placement criteria that VA will consider when determining at which Vet Center the scholarship recipient will work to carry out their service obligation. This placement criteria would include the priority criteria in proposed paragraph (a) of this section. There would also be an additional criterion to ensure that standards for supervision required for professional licensure are met. VA would consider the size and professional makeup of the current Vet Center staff to ensure that the Vet Center staff has health care professionals that are licensed to supervise participants of the RCSSP from the same health care profession as required by VA professional qualification standards for licensure for each of the four aforementioned professions. The additional placement criterion would ensure that the participants are placed in Vet Centers where they would have direct supervision by health care providers within their same profession as required by the VA professional qualification standards.

Proposed paragraph (c) would be in alignment with 38 U.S.C. 7699(c)(1) by establishing the funds covered under the RCSSP. We would state that the funds would cover the costs of an individual obtaining a terminal doctorate degree (as defined in the qualification standards) in psychology; and a terminal master level degree in social work, marriage and family therapy, or professional mental health counseling. We would also state that VA would pay a participant of the RCSSP for a maximum of two years. We note that RCSSP payments are paid prospectively and does not cover the past costs of the participant's education and expenses accrued pre-award. Therefore, if a scholarship recipient applies and is selected to the RCSSP in the middle of their degree program, VA would only pay for the tuition payments still outstanding. VA would not reimburse the scholarship recipient for tuition payments already paid. Furthermore, if the scholarship recipient completes the degree early or is receiving a partial scholarship from a different source, VA would only pay for the actual expenses owed by the recipient. We would also state that if a participant completes their terminal degree in less than two years, the period of obligated service remains unchanged.

In proposed paragraph (c)(1), VA would state that social work, marriage and family therapy, and professional mental health counseling are master level programs that require an approximate two-year period for achieving the terminal degree. VA would fund RCSSP social work, marriage and family therapy, and professional mental health counseling participants for a maximum of two years.

In proposed paragraph (c)(2), we would state that psychology is a doctoral level program requiring approximately five years for completion of the terminal academic degree. However, to equalize the award and obligated service requirements across all four professions, VA would also state that, although psychology is a doctoral level program requiring approximately five years for completion for the terminal academic degree, VA funding for RCSSP psychology participants would only be for the last two years of their academic training for the terminal doctorate degree.

We note that psychology graduates are also required to participate in a one-year residency at either an American Psychology Association (APA) or Canadian Psychological Association (CPA) accredited program prior to qualifying for full time VA employment. The internship is under separate funding authority and VA would, therefore, not provide funding for the one-year internship. Additionally, in order to obtain an APA or CPA accredited internship, an individual must participate in the Association of Psychology Postdoctoral and Internship Centers (APPIC) process where they can match with an internship program . An individual who participates in the APPIC process is not guaranteed to match with an APA or CPA accredited internship. Should a scholarship participant not receive a match with an APA or CPA accredited internship, they would be considered in breach of their agreement because they would not be eligible to work at VA and would be unable to fulfil their period of obligated service at a Vet Center.

Proposed paragraph (d) would state what would constitute a payment for the RCSSP. We would state that participants would be exempt from Federal taxation. We would also state that payment would consist of the actual cost of tuition and required fees; other educational expenses, including books and laboratory equipment; and a

monthly stipend, for the duration of the scholarship award. We would specify that the Secretary may determine the amount of the stipend paid to participants, but that amount may not exceed the maximum amount provided for in 38 U.S.C. 7613(b). This proposed paragraph is in alignment with similar scholarship programs. See § 17.606(a).

Section 17.551 Agreement and Obligated Service

Section 7699(c) of 38 U.S.C. establishes the agreement criteria for participants of the RCSSP. We would state these criteria in proposed § 17.551(a) as follows: (1) Proposed paragraph (a)(1) would state that the participant of the RCSSP must agree to maintain enrollment, attendance, and acceptable level of academic standing as defined by the school. (2) Proposed paragraph (a)(2) would state that the participant must obtain a terminal degree in psychology, social work, marriage and family therapy, or professional mental health counseling. For psychology, a terminal degree means a doctorate degree and for social work, marriage and family therapy, and professional mental health counseling a terminal degree means a masters level degree. (3) Proposed paragraph (a)(3) would state that the participant must be employed as a full-time VA employee at a Vet Center for a period of six-years as a psychologist, social worker, marriage and family therapist, or professional mental health counselor following the completion of such program of study. (4) Lastly, proposed paragraph (a)(4) would state psychologists must complete a one-year internship at either an APA or CPA accredited program. We would add that obtaining an APA or CPA accredited internship requires that an individual participate in the APPIC process. If a scholarship participant does not participate in an APA or CPA accredited internship, they are in breach of their agreement. We note that participation in an APA or CPA accredited internship is a requirement for VA employment. Section 7699A of 38 U.S.C. establishes the period of obligated service for a participant of the RCSSP. We would restate § 7699A(b)(1) in proposed § 17.551(b)(1) by stating that VA will notify the participant of the commencement date of the period of obligated service no later than 60 days before such date.

Section 7699A(a) establishes the obligated service for the RCSSP. However, the statute is silent as how soon after the participant completes their terminal degree the period of obligated service should commence. We would, therefore, state in proposed § 17.551(b)(2)(i) that the participant's period of obligated service will begin on the date the participant begins full-time permanent employment at a Vet Center as a psychologist, social worker, marriage and family therapist, or professional mental health counselor, but no later than 180 days after the date that the participant completes a terminal degree in one of the identified disciplines.

We would also state that all RCSSP psychology participants would assume their period of obligated service within 180 days following completion of their one-year APA or CPA internship, which requires completion of all academic requirements to obtain a terminal doctorate degree. This includes completion of all academic requirements and the dissertation required for graduation with a terminal doctorate degree. A participant's failure to meet these requirements, would be considered a breach of their acceptance agreement. VA has used similar language in other VA scholarship programs. See § 17.607(b)(1).

We would also describe in proposed § 17.551(b)(2)(i)(ii) the period of clinical supervision by a licensed health care professional of the same discipline. This period of clinical supervision is aligned with State licensure requirements for each of the health care professions covered under the RCSSP and a requirement for maintaining VA employment. We would state in proposed § 17.551(b)(2)(ii) that, upon receipt of the terminal degree, participants will enter VA employment at the entry level until full licensure at the independent practice level has been attained. We would add that independent practice licensure is a requirement for all scholarship participants. Also, non-licensed psychologists, social workers, marriage and family therapists, and professional mental health counselors are required to serve under the supervision of a licensed health care professional of their profession and must be independently licensed by a State within the time frame specified in VA qualification standards.

VA understands that obtaining a terminal degree and the required license for each health care profession can be challenging. As such, VA will actively monitor all RCSSP participants to make certain that the participant abides by the requirements of the acceptance agreement. We would state in proposed § 17.551(b)(2)(iii) that VA will actively assist and monitor participants to ensure State licenses are obtained in a minimal amount of time following graduation and required supervision. We would add that if a participant fails to obtain their terminal degree or fails to obtain licensure in a State at the independent practice level no later than 180 days after the required period of supervision for their profession, the participant is considered to be in breach of the acceptance agreement. This language is similar to that of other VA scholarship programs. See § 17.607(b)(1).

In alignment with similar scholarship programs, we would state that VA reserves the right to make final decisions on the location and position of the obligated service. See 38 CFR 17.607(d). VA believes that is necessary to reserve the right to make final decisions on the location to achieve the intent of the Commander John Scott Hannon Veterans Mental Health Care Improvement Act of 2019. VA must be able to have control over where it places the individuals to ensure VA beneficiaries' health care needs are met in locations that are within a reasonable proximity to the beneficiaries' residence. We would also state that a participant who receives an RCSSP must be willing to relocate to another geographic location to carry out their service obligation in accordance with the participant's mobility agreement. Because participants must be supervised by a licensed health care profession, we would add that there is a VA requirement for participants to receive supervision from a licensed staff within their respective professions.

Section 17.553 Failure To Comply With Terms and Conditions of Agreement

Section 7699B provides for the repayment of RCSS funds should the participant be in breach of their agreement. Proposed § 17.553 would mirror § 7699B(a) with minor changes. Proposed § 17.553(a) would state the liquidated damages payable to the United States. We would state that except as provided in § 17.553(b), a participant of the RCSSP who fails to accept payment, or instructs the educational institution in which the participant is enrolled not to accept payment, in whole or in part, of a scholarship under the agreement entered into under § 17.551 will be liable to the United States for liquidated damages in the amount of $1,500. Section 7669B(a)(2) states that liability under paragraph (1) is in addition to any period of obligated service or other obligation or liability under such agreement. However, in alignment with other scholarship programs, VA does not seek/impose liquidation damages in addition to any other service obligation

or financial liability. We do not think it prudent to add an additional financial burden to a participant for failure to accept RCSSP funds. We would, therefore, not include this provision as part of the liquidated damages provision in § 17.553(a).

Proposed § 17.553(b) provides for the liability payable to the United States if the participant breaches their agreement during the period of program study and would mirror § 7699B(b) with minor stylistic changes. We would state that except as provided in § 17.553(d), a participant of the RCSSP will be liable to the United States for the amount that has been paid to or on behalf of the participant under the agreement if the participant fails to maintain an acceptable level of academic standing in the educational institution in which the participant is enrolled, as determined by the educational institution; the participant is dismissed from the educational institution for disciplinary reasons; or the participant voluntarily terminates the program of study in the educational institution before the completion of the program of study for which the RCSSP was awarded. We would add that liability under § 17.553(b) is in lieu of any service obligation arising under the agreement.

Proposed § 17.553(c) provides for the liability payable to the United States if the participant breaches their agreement during the period of obligated service and would mirror § 7699B(c) with minor stylistic changes. We would state that except as provided in § 17.553(d), if a participant of the RCSSP does not complete their period of obligated service, the United States will be entitled to recover from the participant an amount determined in accordance with the following formula: $A = 3\Phi(t - s/t)$, where 'A' is the amount the United States is entitled to recover; 'Φ' is the sum of: The amounts paid under this subchapter to or on behalf of the participant; and the interest on such amounts, which would be payable if, at the time the amounts were paid, they were loans bearing interest at the maximum legal prevailing rate, as determined by the Treasurer of the United States; 't' is the total number of months in the period of obligated service of the participant; and 's' is the number of months of such period served by the participant.

Proposed § 17.553(d) provides for the limitation on liability payable to the United States due to reductions in force and would mirror § 7699B(d) with minor stylistic changes. We would state that liability will not arise under § 17.553(c) if the participant fails to maintain employment as a VA employee due to a staffing adjustment.

Proposed § 17.553(e) provides for the repayment period on damages owed to the United States and would mirror § 7699B(e) with minor stylistic changes. We would state that the participant will pay the amount of damages that the United States is entitled to recover under § 17.553 in full to the United States no later than one year after the date of the breach of the agreement.

Executive Orders 12866 and 13563

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 proposed rule is not a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would 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 RCSSP will solely be operated and administered within 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.

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 proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This proposed rule includes provisions constituting a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) that require approval by the Office of Management and Budget (OMB). Accordingly, under 44 U.S.C. 3507(d), VA has submitted a copy of this rulemaking action to OMB for review.

OMB assigns control numbers to collections of information it approves. VA 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. Proposed §§ 17.548 and 17.551 contain a new collection of information. If OMB does not approve the collection of information as requested, VA will immediately remove the provisions containing a collection of information or take such other action as is directed by OMB.

Comments on the new collection of information contained in this rulemaking should be submitted through *www.regulations.gov.* Comments should indicate that they are submitted in response to ''RIN 2900–AR31- Readjustment Counseling Service Scholarship Program'' and should be sent within 60 days of publication of this rulemaking. The collection of information associated with this rulemaking can be viewed at: *www.reginfo.gov/public/do/PRAMain.*

OMB is required to make a decision concerning the collection of information contained in this rulemaking 60 days after publication of this rulemaking in the **Federal Register** (FR). Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment on the provisions of this rulemaking.

The Department considers comments by the public on new collections of information in:

- Evaluating whether the new collections of information are necessary for the proper performance of the functions of the Department, including whether the information will have practical utility;
- Evaluating the accuracy of the Department's estimate of the burden of the new collections of information, including the validity of the methodology and assumptions used;
- Enhancing the quality, usefulness, and clarity of the information to be collected; and
- Minimizing the burden of the collections of information on those who are to respond, including through the

use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

The collection of information contained in 38 CFR 17.548 and 17.551 is described immediately following this paragraph, under its respective title.

Title: Readjustment Counseling Service Scholarship Program (RCSSP).

OMB Control No: 2900–xxxx (New/TBD).

CFR Provision: 38 CFR 17.548 and 17.551.

- *Summary of collection of information:* The RCSSP would provide educational assistance to individuals who pursue a graduate degree in psychology, social work, marriage and family therapy, or mental health counseling that would meet the education requirements for appointment as a health care professional in VA Vet Centers.
- *Description of need for information and proposed use of information:* This information would be collected for applicants who wish to participate in the RCSSP. The information would also be collected for those individuals who are selected to participate in the RCSSP and who must sign an agreement between VA and the eligible individual. This agreement would hold the eligible individual accountable for upholding the terms and conditions of the agreement and alert the eligible individual of the consequences of a breach in the agreement.
- *Description of likely respondents:* Eligible individuals who apply for the RCSSP and those individuals who are ultimately accepted for participation in the RCSSP.
- *Estimated number of respondents:* 50 Applicants, 5 Selected Participants from the 50 Applicants.
- *Estimated frequency of responses:* Applicants and Selected Participants: 1 time.
- *Estimated average burden per response:*

Applicants: 3 hours.

Selected Participants: 1.6 hours.

- *Estimated total annual reporting and recordkeeping burden:* 158 hours.

Applicants: 150 hours.

Selected Participants: 8 hours.

- *Estimated cost to respondents per year:* VA estimates the annual cost to all respondents will be $4,277 per year (158 burden hours × $27.07 per hour). VA used the Bureau of Labor Statistics (BLS) median hourly wage for hourly wage for ''all occupations'' of $27.07 per hour. This information is available at *https://www.bls.gov/oes/current/oes_nat.htm#13-0000.*

Catalog of Federal Domestic Assistance

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

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Health care, Health facilities, Health professions, Scholarships and fellowships.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on October 26, 2021, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Consuela Benjamin,

Regulations Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs proposes to amend 38 CFR part 17 as set forth below:

PART 17—MEDICAL

■ 1. The general authority citation for part 17 continues and an entry for §§ 17.545 through 17.553 is added in numerical order, to read as follows:

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

* * * * *

Sections 17.545 through 17.553 are also issued under 38 U.S.C. 7698, 7699, 7699A, and 7699B.

* * * * *

■ 2. Add an undesignated center heading and §§ 17.545 through 17.553 immediately following § 17.539 to read as follows:

Sec.

* * * * *

Readjustment Counseling Service Scholarship Program

§ 17.545 Purpose.

The purpose of §§ 17.545 through 17.553 is to establish the Readjustment Counseling Service Scholarship Program (RCSSP) as part of VA's Educational Assistance Program. For purposes of the RCSSP, the term Vet Center has the meaning given that term in 38 U.S.C. 1712A(h).

§ 17.547 Eligibility.

An individual is eligible to participate in the RCSSP if the individual meets the following requirements.

(a) Is accepted for enrollment or be currently enrolled on a full-time basis in a program of study at an accredited educational institution, school, or training program leading to a terminal doctorate degree in psychology, or a terminal masters degree in social work, marriage and family therapy, or mental health counseling that would meet the education requirements for appointment to a position in one of those fields under 38 U.S.C. 7402(b); and

(b) Enters into an agreement with the Secretary under § 17.551.

§ 17.548 Application procedures.

(a) *Availability.* VA will make awards under the RCSSP only when VA determines it is necessary to assist in alleviating shortages of psychologists, social workers, marriage and family therapists, or mental health counseling professionals in Vet Centers. VA's determination of the number of RCSSP scholarships to be awarded in a fiscal year is subject to the availability of appropriations.

(b) *Application-general.* Each individual desiring a RCSSP scholarship must submit an accurate and complete application, including a signed written acceptance agreement.

(c) *VA's duties.* VA will notify applicants prior to acceptance in the RCSSP of the following information:

(1) A fair summary of the rights and liabilities of an individual whose application is approved by VA and whose acceptance agreement is consummated by VA; and

(2) Full description of the terms and conditions that apply to participation in the RCSSP and service in VA.

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–XXXX.)

§ 17.549 Award Procedures.

(a) *Priority.* In selecting individuals to participate in the RCSSP VA will give priority to the following individuals:

(1) An individual who agrees to be employed by Vet Centers located in communities that are:

(i) Designated as a medically underserved population under § 330(b)(3) of the Public Health Service Act (42 U.S.C. 254b(b)(3)); and

(ii) In States with a per capita population of more than five percent veterans according to the National Center for Veterans Analysis and Statistics and the Bureau of the Census.

(2) A veteran.

(b) *Placement criteria.* When determining which Vet Center a scholarship recipient will be placed to carry out their service obligation, VA will consider the priority criteria in paragraph (a) of this section and the size and professional makeup of the current Vet Center staff to ensure that the Vet Center staff has health care professionals that are licensed to supervise participants of the RCSSP from the same health care profession as required by VA professional qualification standards for licensure for each of the four professions.

(c) *Amount of funds.* VA will provide a scholarship to individuals who participate in the RCSSP to cover the actual costs of such individuals obtaining a terminal degree in psychology, social work, marriage and family therapy, or professional mental health counseling for a maximum of two years. If a participant completes their terminal degree in less than two years, the period of obligated service remains unchanged.

(1) Social work, marriage and family therapy, and professional mental health counseling are master level programs that require approximately a two-year period for achieving the terminal degree. VA will fund RCSSP social work, marriage and family therapy, and professional mental health counseling participants for a maximum of two years.

(2) Psychology is a doctoral level program requiring approximately five years for completion of the terminal academic degree. In addition, psychology graduates are required to undergo a one-year residency at either an American Psychology Association (APA) or Canadian Psychological Association (CPA) accredited internship program prior to qualifying for full time VA employment. VA will fund psychology participants for the last two years of their five- year academic training to obtain a terminal doctorate degree. VA will not provide funding for the one-year APA or CPA internship under the RCSSP.

(d) All such payments to scholarship participants are exempt from Federal taxation. The payments will consist of the actual cost of:

(1) Tuition and required fees;

(2) Other educational expenses, including books and laboratory equipment; and

(3) A monthly stipend, for the duration of the scholarship award. The Secretary may determine the amount of the stipend paid to participants, but that amount may not exceed the maximum amount provided for in 38 U.S.C. 7613(b).

§ 17.551 Agreement and obligated service.

(a) *Agreement.* Each participant who accepts funds from the RCSSP will enter into an agreement with VA where the participant agrees to the following:

(1) Maintain enrollment, attendance, and an acceptable level of academic standing as defined by the school;

(2) Obtain a terminal degree in psychology, social work, marriage and family therapy, or professional mental health counseling; and

(3) Be employed as a full-time VA employee at a Vet Center for a period of six-years as a psychologist, social worker, marriage and family therapist, or professional mental health counselor following the completion of such program of study.

(4) Psychologists must complete a one-year internship at either an American Psychological Association (APA) or Canadian Psychological Association (CPA) accredited program. Obtaining an APA or CPA accredited internship requires that an individual participate in the Association of Psychology Postdoctoral and Internship Centers (APPIC) process. If a scholarship participant does not participate in an APA or CPA accredited internship, they are in breach of their agreement.

(b) *Obligated service.* (1) *Determination of service commencement date.* VA will notify the participant of the commencement date of the period of obligated service no later than 60 days before such date.

(2) *Commencement date of obligated service.* (i) *General.* A participant's period of obligated service will begin on the date the participant begins full-time permanent employment at a Vet Center as a psychologist, social worker, marriage and family therapist, or professional mental health counselor, but no later than 180 days after the date that the participant completes a terminal degree in one of the identified disciplines. Psychology participants will commence their period of obligated service no later than 180 days after completion of their one-year APA or CPA internship, which requires completion of all academic requirements to obtain a terminal doctorate degree.

(ii) *Independent practice.* Upon receipt of the terminal degree participants will enter VA employment at the entry level until full licensure at the independent practice level has been attained. Independent practice licensure is a requirement for all scholarship participants. Non-licensed psychologists, social workers, marriage and family therapists, and professional mental health counselors are required to serve under the supervision of a licensed health care professional of their profession and must be independently licensed by a State within the time frame specified in VA qualification standards.

(iii) *VA monitoring of participants.* VA will actively assist and monitor participants to ensure State licenses are obtained in a minimal amount of time following graduation and the required period of supervision for their profession. If a participant fails to obtain their terminal degree or fails to obtain licensure in a State at the independent practice level no later than 180 days after the required period of supervision for their profession, the participant is considered to be in breach of the acceptance agreement.

(3) *Location and position of obligated service.* VA reserves the right to make final decisions on the location and position of the obligated service. A participant who receives an RCSSP must be willing to relocate to another geographic location to carry out their service obligation in accordance with the participant's agreement. The requirement for participants to receive supervision from a licensed staff within their respective professions, as a condition for their own licensure, is a critical point for the consideration of the potential location of the obligated service.

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

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

(a) *Liquidated damages.* Except as provided in paragraph (b) of this section, a participant of the RCSSP who fails to accept payment, or instructs the educational institution in which the participant is enrolled not to accept payment, in whole or in part, of a scholarship under the agreement entered into under § 17.551 will be liable to the United States for liquidated damages in the amount of $1,500.

(b) *Liability during program of study.* Except as provided in paragraph (d) of this section, a participant of the RCSSP will be liable to the United States for the amount that has been paid to or on behalf of the participant under the agreement if any of the following occurs: Liability under paragraph (b) of this section is in lieu of any service obligation arising under the agreement.

(1) The participant fails to maintain an acceptable level of academic standing in the educational institution in which the participant is enrolled, as

determined by the educational institution;

(2) The participant is dismissed from the educational institution for disciplinary reasons; or

(3) The participant voluntarily terminates the program of study in the educational institution before the completion of the program of study for which the RCSSP was awarded.

(c) *Liability during period of obligated service.* Except as provided in paragraph (d) of this section, if a participant of the RCSSP does not complete their period of obligated service, the United States will be entitled to recover from the participant an amount determined in accordance with the following formula: $A = 3\Phi(t - s/t)$, where:

(1) 'A' is the amount the United States is entitled to recover;

(2) 'Φ' is the sum of (i) the amounts paid under this subchapter to or on behalf of the participant, and (ii) the interest on such amounts, which would be payable if at the time the amounts were paid they were loans bearing interest at the maximum legal prevailing rate, as determined by the Treasurer of the United States.

(3) 't' is the total number of months in the period of obligated service of the participant; and

(4) 's' is the number of months of such period served by the participant.

(d) *Limitation on liability for reductions-in-force.* Liability will not arise under Section 17.553(c) if the participant fails to maintain employment as a VA employee due to a staffing adjustment.

(e) *Repayment period.* The participant will pay the amount of damages that the United States is entitled to recover under § 17.553 in full to the United States no later than one year after the date of the breach of the agreement.

[FR Doc. 2021–23822 Filed 11–4–21; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2021–0452; FRL–8834–01–R9]

Air Plan Approval; California; Opacity Testing of Heavy-Duty Diesel Vehicles

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the California State Implementation Plan (SIP) concerning particulate matter (PM) emissions from heavy-duty (HD) diesel vehicles. We are proposing to approve state rules to regulate these emission sources under the Clean Air Act (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Comments must be received on or before December 6, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2021–0452 at *https://www.regulations.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* 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, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Jeffrey Buss, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4152 or by email at *buss.jeffrey@epa.gov.*

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

Table of Contents

I. The State's Submittal

A. What rules did the State submit?

Table 1 lists the rules addressed by this proposal with the dates that they were adopted by the California Air Resources Board (CARB) and submitted to the EPA.

TABLE 1—SUBMITTED RULES

Agency	Rule No.	Rule title	Amended	Submitted
CARB	Title 13, Division 3, Chapter 3.5.	Heavy-Duty Diesel Smoke Emission Testing and Heavy-Duty Vehicle Emission Control System Inspections [1].	07/01/2019	02/13/2020
CARB	Title 13, Division 3, Chapter 3.6.	Periodic Smoke Inspections of Heavy-Duty Diesel-Powered Vehicles [2].	07/01/2019	02/13/2020

On August 13, 2020, the submittal from CARB was deemed by operation of law to meet the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review.

B. Are there other versions of these rules?

There are no previous versions of the submitted rules in the California SIP.

C. What is the purpose of the submitted rules?

Emissions of PM, including PM equal to or less than 2.5 microns in diameter ($PM_{2.5}$) and PM equal to or less than 10 microns in diameter (PM_{10}), contribute to effects that are harmful to human

[1] Chapter 3.5 contains sections 2180–2189.

[2] Chapter 3.6 contains sections 2190–2194.

health and the environment, including premature mortality, aggravation of respiratory and cardiovascular disease, decreased lung function, visibility impairment, and damage to vegetation and ecosystems. Section 110(a) of the CAA requires states to submit regulations that control PM emissions. The EPA's technical support document (TSD) has more information about these rules.

II. The EPA's Evaluation and Action

A. How is the EPA evaluating the rules?

Rules in the SIP must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)), and must not modify certain SIP control requirements in nonattainment areas without ensuring equivalent or greater emissions reductions (see CAA section 193).

Guidance and policy documents that we used to evaluate enforceability, revisions, relaxation and rule stringency requirements for the applicable criteria pollutants include the following:

1. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' (a.k.a., Bluebook) EPA OAQPS, May 25, 1988.
2. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' (a.k.a., Little Bluebook), EPA Region 9, August 21, 2001.
3. ''Guidance to States on In-Use Smoke Test Procedure for Highway Heavy-Duty Diesel Vehicles,'' EPA OAR, April 3, 1997.
4. ''Guidance to States on Smoke Opacity Cutpoints to be used with the SAE J1667 In-Use Smoke Test Procedure,'' EPA OAR, February 25, 1999.

B. Do the rules meet the evaluation criteria?

These rules meet CAA requirements and are consistent with relevant guidance regarding enforceability and SIP revisions. The standards set forth in the rules listed above (referred to as the ''heavy-duty vehicle inspection program'' (HDVIP) and the ''periodic smoke inspection program'' (PSIP)) are more stringent than the opacity standards set forth in the EPA's guidance to states.[3] Further, while EPA's 1999 guidance establishes recommendations for states to uniformly establish opacity standards, states have authority under CAA section 209(d) to establish their own in-use standards for motor vehicles. The TSD has more information on our evaluation.

C. The EPA's Recommendations To Further Improve the Rules

The TSD includes recommendations for the next time CARB modifies the rules.

D. Public Comment and Proposed Action

As authorized in section 110(k)(3) of the Act, the EPA proposes to fully approve the submitted rules because they fulfill all relevant requirements. We will accept comments from the public on this proposal until December 6, 2021. If we take final action to approve the submitted rules, our final action will incorporate these rules into the federally enforceable SIP.

III. Incorporation by Reference

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

IV. Statutory and Executive Order Reviews

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

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

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

List of Subjects in 40 CFR Part 52

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

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

Dated: October 29, 2021.

Deborah Jordan,

Acting Regional Administrator, Region IX.

[FR Doc. 2021–23996 Filed 11–4–21; 8:45 am]

BILLING CODE 6560–50–P

[3] ''Guidance to States on Smoke Opacity Cutpoints to be used with the SAE J1667 In-Use Smoke Test Procedure,'' EPA OAR, February 25, 1999.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60 and 63

[EPA–HQ–OAR–2021–0382; FRL–7547.1–02–OAR]

RIN 2060–AV37

Potential Future Regulation Addressing Pyrolysis and Gasification Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking; extension of public comment period.

SUMMARY: On September 8, 2021, the U.S. Environmental Protection Agency (EPA) solicited information and requested comments to assist in the potential development of regulations for pyrolysis and gasification units that are used to convert solid or semi-solid feedstocks to useful products such as energy, fuels, and chemical commodities. The deadline to respond to our request was November 8, 2021. The EPA is extending the period to respond to our request for information and comment to December 23, 2021.

DATES: The public comment period for the request for information published in the **Federal Register** on September 8, 2021 (86 FR 50296), originally ending November 8, 2021, is being extended. Written comments must be received on or before December 23, 2021.

ADDRESSES:

Comments. You may send comments, identified by Docket ID No. EPA–HQ–OAR–2021–0382, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2021–0382 in the subject line of the message.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2021–0382.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA–HQ–OAR–2021–0382, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery or Courier (by scheduled appointment only):* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal holidays).

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR- 2021–0382. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov/,* including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically any information that you consider to be CBI or other information whose disclosure is restricted by statute. This type of information should be submitted by mail as discussed below.

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.*

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and should be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

Out of an abundance of caution for members of the public and EPA staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. The EPA's Docket Center staff will continue to provide remote customer service via email, phone, and webform. The Agency encourages the public to submit comments via *https://www.regulations.gov/* or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.* The EPA continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention, local area health departments, and our Federal partners so that the Agency can respond rapidly as conditions change regarding COVID–19.

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2021–0382. Note that written comments containing CBI and submitted by mail may be delayed and no hand deliveries will be accepted.

FOR FURTHER INFORMATION CONTACT: For questions about this action, contact Nabanita Modak Fischer, Fuels and Incineration Group, Sector Policies and Programs Division (E143–05), Environmental Protection Agency,

Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5572; fax number: (919) 541–3470; email address: *modak.nabanita@epa.gov.*

SUPPLEMENTARY INFORMATION: On September 8, 2021, the EPA published an advance notice of proposed rulemaking (ANPRM) soliciting information and requesting comments to assist in the potential development of regulations for pyrolysis and gasification units that are used to convert solid or semi-solid feedstocks to useful products such as energy, fuels, and chemical commodities (86 FR 50296). In accordance with that Notice, the comment period to respond to the ANPRM currently closes on November 8, 2021. The EPA has received a request to extend the comment period. After considering the request to extend the public comment period, the EPA has decided to extend the public comment period until December 23, 2021. This extension will provide the additional time requested by the public to review the request and gather information to respond.

Penny Lassiter,

Director, Sector Policy and Programs Division.

[FR Doc. 2021–24253 Filed 11–4–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 4

[PS Docket Nos. 21–346, 15–80; ET Docket No. 04–35; FCC 21–99; FR ID 55366]

Resilient Networks; Disruptions to Communications; Disruptions to Communications

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission seeks comment on: potential improvements to the voluntary Wireless Network Resiliency Cooperative Framework (Framework), including evaluating what triggers its activation, its scope of participants, whether existing Framework elements can be strengthened, any gaps that need to be addressed, and whether the public would benefit from codifying some or all of the Framework; ways to enhance the information available to the Commission through the Network Outage Reporting System (NORS) and Disaster Information Reporting System (DIRS) during disasters and network outages to improve situational awareness; and communications resiliency strategies for power outages, including improved coordination between communications service providers and power companies and deploying onsite backup power or other alternative measures to reduce the frequency, duration, or severity of power-related disruptions to communications services.

DATES: Submit comments on or before December 6, 2021, and reply comments on or before January 4, 2022.

ADDRESSES: You may submit comments, identified by PS Docket Nos. 21–346 and 15–80; ET Docket No. 04–35, by any of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *http://apps.fcc.gov/ecfs/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing.

Filings can be sent by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 45 L Street NE, Washington, DC 20554.
- Effective March 19, 2020, and until further notice, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID–19. See FCC Announces Closure of FCC Headquarters Open Window and Change in Hand-Delivery Policy, Public Notice, DA 20–304 (March 19, 2020). *https://www.fcc.gov/document/fcc-closes-headquarters-open-window-and-changes-hand-delivery-policy.*

People with disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or calling the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

FOR FURTHER INFORMATION CONTACT: For further information, contact Saswat Misra, Attorney-Advisor, Cybersecurity and Communications Reliability Division, Public Safety and Homeland Security Bureau, (202) 418–0944 or via email at *Saswat.Misra@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking (*NPRM*), in PS Docket Nos. 21–346 and 15–80; ET Docket No. 04–35; FCC 21–99, adopted on September 30, 2021 and released on October 1, 2021. The full text of this document is available by downloading the text from the Commission's website at: *https://docs.fcc.gov/public/attachments/FCC-21-99A1.pdf.* When the FCC Headquarters reopens to the public, the full text of this document will also be available for public inspection and copying during regular business hours in the FCC Reference Center, 45 L Street NE, Washington, DC 20554.

Synopsis

I. Introduction

1. With this Notice of Proposed Rulemaking (*NPRM*), we propose steps to improve the reliability and resiliency of communications networks during emergencies. We address these matters against the backdrop of Hurricane Ida, which hit the United States as a Category 4 hurricane and caused significant flooding and damage in several states along the Gulf Coast and the northeastern corridor of the United States. Hurricane Ida demonstrated that, while service providers' ability to restore communications in the aftermath of a devastating storm has improved, more can be done to help ensure that communications networks are sufficiently survivable to provide some continuity of service during major emergencies and to enhance the ability of service providers to restore communications when they fail.

2. Specifically, we consolidate several lines of prior inquiry to initiate this rulemaking regarding the reliability, resiliency, and continuity of communications networks. Hurricane Ida is only the most recent disaster that resulted in failures precisely when Americans most need to communicate. Recent hurricane and wildfire seasons, earthquakes in Puerto Rico, and severe winter storms in Texas demonstrate that America's communications infrastructure remains susceptible to disruption during disasters. These disruptions can prevent or delay the transmission of 911 calls, first responder communications, Emergency Alert System (EAS) and Wireless Emergency Alert (WEA) messages, and other potentially life-saving information. They also can have cascading detrimental effects on the economy and other critical infrastructures due to

interdependencies among sectors, including the transportation, medical, and financial sectors. These disruptions may involve many or all communications networks—including wireline, wireless, cable, satellite, or broadcast facilities.

3. Accordingly, in this NPRM, we seek comment on measures to help ensure that communications services remain operational when disasters strike. We consider whether elements of the Wireless Network Resiliency Cooperative Framework (Framework)—a voluntary agreement developed by the wireless industry in 2016 to provide mutual aid in the event of a disaster—could be improved to enhance the reliability of communication networks. 31 FCC Rcd 13745 (2016) (*Framework Order*). We also ask whether the public would benefit from codifying some or all of the Framework into our rules. Next, we seek comment on how the Commission can better promote situational awareness during disasters through its Disaster Information Reporting System (DIRS) and Network Outage Reporting System (NORS). Finally, we explore communications resilience strategies to address one of the primary reasons for service disruptions: Electric power outages.

II. Background

4. Resilient communications networks are critical to economic growth, national security, emergency response, and nearly every facet of modern life. The Commission has long been concerned with enhancing the reliability and resiliency of the Nation's communications infrastructure. In 2004, the Commission adopted rules that require certain communications providers to supply the Commission with outage reports to address ''the critical need for rapid, complete, and accurate information on service disruptions that could affect homeland security, public health or safety, and the economic well-being of our Nation, especially in view of the increasing importance of non-wireline communications in the Nation's communications networks and critical infrastructure.'' 69 FR 68859 (Nov. 26, 2004) (*2004 Part 4 Report and Order*). Under these rules, service providers must submit outage reports to the Commission through NORS for outages that exceed specified duration and magnitude thresholds. 47 CFR 4.9. The Commission analyzes NORS outage reports to, in the short term, assess the magnitude of major outages, and in the long-term, identify network reliability trends and determine whether the outages likely could have been prevented or mitigated had the service providers followed certain network reliability best practices.

5. In 2007, in the wake of Hurricane Katrina, the Commission established DIRS as a web-based means for service providers, including wireless, wireline, broadcast, and cable providers, to voluntarily report to the Commission their communications infrastructure status, restoration information, and situational awareness information specifically during times of crisis. The Commission recently required a subset of service providers that receive Stage 2 funding from the Uniendo a Puerto Rico Fund or the Connect USVI Fund to report in DIRS when it is activated in their respective territories. 34 FCC Rcd 9109, 9174, 9176–77, paras. 133, 138–140 (2019) (*Puerto Rico & USVI USF Fund Report and Order*). The Commission typically activates DIRS for affected counties in the event of major emergencies. These announcements often note that the Commission is suspending its rules on network outage reporting for DIRS participants during the activation period.

6. DIRS data have provided critical situational awareness during communications outages, even when information is shared only on an aggregated or limited basis. The Commission's analysis informs restoration efforts by federal partners and the agency's own assessments of communications reliability during disasters. For example, the Commission prepares and provides aggregated DIRS information, without company-identifying information, to the Department of Homeland Security (DHS), which then distributes the information to a DHS-led group of federal agencies tasked with coordinating disaster response efforts, including other units in DHS, during incidents. This DHS-led group is the Emergency Support Function #2 (ESF–2), which is composed of other participants including the Department of Agriculture, Department of Commerce, Department of Defense, General Services Administration, Department of Interior, and the Federal Communications Commission. Agencies use the analyses for their situational awareness and for determining restoration priorities for communications services and infrastructure in affected areas. The Commission also provides aggregated data, without company-identifying information, to the public during disasters. Recently, the Commission established a framework to provide additional federal, state, Tribal, and territorial partners with access to the critical NORS and DIRS information they need to ensure the public's safety while preserving the presumptive confidentiality of the information.

7. Also following Hurricane Katrina in 2007, the Commission adopted backup power obligations in limited contexts. In 2007, the Commission adopted a rule requiring Commercial Mobile Radio Service (CMRS) providers and local exchange carriers to maintain emergency backup power for a minimum of 24 hours for assets inside central offices and eight hours for cell sites, remote switches, and digital loop carrier system remote terminals. After observing the severe impact on 911 networks across the Midwest caused by the 2012 derecho storm, the Commission took steps to promote 911 network reliability and resiliency by requiring covered 911 service providers to take reasonable measures to provide reliable 911 service, including through providing for central office backup power. 47 CFR 9.19(a)(4) (defining a ''covered 911 service provider'' as an entity that provides 911, E911, or [Next Generation 911 (NG911)] capabilities such as call routing, automatic location information (ALI), automatic number identification (ANI), or the functional equivalent of those capabilities, directly to a [Public Safety Answering Point (PSAP)], statewide default answering point, or appropriate local emergency authority, or an entity that operates one or more central offices that directly serve a PSAP). Covered 911 service providers must annually certify to the Commission that they have taken ''reasonable measures to provide reliable 911 service with respect to 911 circuit diversity, availability of central office backup power, and diverse network monitoring,'' or they must certify to taking alternative measures that ''are reasonably sufficient to mitigate the risk of failure or that one or more certification elements are not applicable to its network.'' 47 CFR 9.19(b). Covered 911 service providers must certify their compliance with backup power standards of 24 hours for central offices that provide administrative lines for Public Safety Answering Points (PSAPs) and 72 hours for central offices that have a selective router that directs 911 calls. 47 CFR 9.19. Further, the Commission has adopted rules requiring that providers of facilities-based, fixed voice service offered as a residential service provide their subscribers the options to purchase, at the point of sale, solutions that provide 8 and 24 hours of backup power for the service. 47 CFR 9.20.

8. In 2013, in the wake of Superstorm Sandy, the Commission again took up

the issue of communications infrastructure resiliency, particularly that of wireless resiliency; specifically, the Commission proposed to require facilities-based Commercial Mobile Radio Service providers to submit to the Commission for public disclosure, on a daily basis during and immediately after major disasters, the percentage of cell sites within their networks that are providing service. On December 14, 2016, in lieu of adopting this proposal, the Commission adopted an Order supporting the voluntary Framework, intended to promote resilient communications and situational awareness during disasters. Framework Order, 31 FCC Rcd at 13745–46, paras. 1–2. The Framework commits its participants to five prongs: providing for reasonable roaming arrangements during disasters when technically feasible; fostering mutual aid during emergencies; enhancing municipal preparedness and restoration; increasing consumer readiness and preparation; and improving public awareness and stakeholder communications on service and restoration status. An emergency or disaster activates the Framework where the Federal Emergency Management Agency (FEMA) activates ESF–2 and the Commission activates DIRS. ESFs provide the structure for coordinating Federal interagency support for a Federal response to an incident. ESF–2 coordinates Federal actions to assist industry in restoring the public communications infrastructure and to assist State, tribal, and local governments with emergency communications and restoration of public safety communications systems and first responder networks.

9. In 2017, the Government Accountability Office (GAO), in conjunction with its review of federal efforts to improve the resiliency of wireless networks during natural disasters and other physical incidents, released a report recommending that the Commission should improve its monitoring of industry efforts to strengthen wireless network resiliency. The GAO found that the number of wireless outages attributed to a physical incident—a natural disaster, accident, or other manmade event, such as vandalism—increased from 189 in 2009 to 1,079 in 2016. The GAO concluded that more robust measures and a better plan to monitor the Framework would help the FCC collect information on the Framework and evaluate its effectiveness, and that such steps could help the FCC decide if further action is needed. In light of prolonged outages during several emergency events in 2017 and 2018, and in parallel with the GAO recommendations, the Public Safety and Homeland Security Bureau (Bureau) conducted several inquiries and investigations to better understand and track the output and effectiveness of the Framework and other voluntary coordination efforts that promote wireless network resiliency and situational awareness during and after these hurricanes and other emergencies. In February 2020, following a series of PSHSB staff coordination meetings with wireless, backhaul and electric service providers to discuss the gaps identified in the above record, CTIA and the Edison Electric Institute formed the Cross-Sector Resiliency Forum on February 27, 2020 and released a 12-step action plan to improving wireless resiliency.

10. In the days leading up to landfall of Hurricane Ida on August 29, 2021, the FCC had begun coordinating response activities with the State of Louisiana, the Federal Emergency Management Agency, the Cybersecurity and Infrastructure Security Agency, and members of the Communications Information Sharing and Analysis Center (Comm-ISAC) and to determine potential impacts, challenges, and mutual aid resources. The Commission had already deployed agents to support the Louisiana Emergency Operations Center (EOC) and to conduct baseline surveys of communications as well as to provide coordination and spectrum management support. Communications companies had also begun pre-positioning mobile communications assets in safe zones just outside the potential impact areas in order to rapidly deploy much-needed services, post landfall. Ida had significant physical impacts on both power and communications infrastructure, which had cascading consequences on interdependent public safety communications infrastructure and services such as PSAPs and Louisiana's land mobile radio public safety communications network.

11. Following Hurricane Ida's departure, the Commission began supporting recovery work in earnest. The Commission reminded communications industry of its commitments in the Framework and encouraged wireless providers, specifically, to activate roaming in areas where cellular communications were hardest hit. Even after roaming had been activated in limited areas, communications remained diminished as communications companies were working to repair, replace, and restore communications infrastructure. Immediately after the storm, 28.1 percent of cell sites were down across the affected counties. Louisiana was hardest hit in this respect, with more than 50 percent of sites down in the affected counties on August 30. At its peak, Louisiana had three PSAPs offline due to damaged power and communications infrastructure, and other PSAPs were impacted and rerouted calls as generators began to fail. Commission personnel communicated with the Louisiana Association of Broadcasters to determine unmet fuel, communications, and power needs of state broadcasters and to facilitate the provision of much needed resources and services.

12. Commission staff also conducted on-the-ground assessments of communications infrastructure to provide emergency management officials intelligence and to assist with the identification of critical communications infrastructure, including responding to additional unintentional damage occurring during repairs to the communications and power infrastructure. The Commission also issued special temporary authorizations (STAs) and, *sua sponte,* numerous orders to provide regulatory relief in support of providers' restoration efforts, including waivers of deadlines and technical requirements, as well as providing relief to impacted consumers. This work remains ongoing as recovery continues.

III. Notice of Proposed Rulemaking

A. Improving the Wireless Network Resiliency Cooperative Framework

13. The voluntary Framework plays a central role in how wireless providers prepare for and respond to emergencies. Over the years, the Commission has examined and re-examined the efficacy of the Framework for purposes of restoring communications during and following disasters. These inquiries suggest that providers take a multifaceted approach to disaster readiness and response, with the aim of improving the public's safety during natural disasters. Wireless provider efforts have included investments in network resiliency, reinforcing network coverage and capacity, conducting site-based preparatory work, and making plans to mitigate commercial power failures, as well as utilizing commercial roaming agreements, working with government partners, and educating consumers on preparedness. These initiatives have helped to keep more Americans connected and informed even during major disasters.

14. However, these inquiries also show that there are both gaps in the

Framework's coverage and, during some recent disasters, delays in its implementation, including technical challenges associated with roaming implementation among signatory companies. Further, as explained below, there are some disaster situations where the Framework, by its owns terms, would not go into effect. These findings from our prior inquiries suggest there may be targeted opportunities to improve the voluntary Framework and network resiliency—not just of wireless networks, but of communications networks as a whole. We seek comment on those opportunities below. We also seek comment on whether the Commission should revisit the voluntary nature of the Framework.

15. *Framework Activation.* Currently, the Framework only applies when both ESF–2 and DIRS are activated. As a result, there may be circumstances where the Framework is not activated but where mutual aid or other support obligations are warranted. For example, the Framework has not been operational during the California power shutoffs and wildfires because ESF–2 was not activated. To address this gap, should we work with carriers to revisit the prerequisites, *e.g.,* the types of emergencies or other declarations (ESF–2 and DIRS activation) that trigger the Framework or that govern the duration of its obligations? If so, what should those triggers and durations be?

16. *Scope of Framework Participants.* We seek comment on whether expanding the scope of the Framework participants could enhance its effectiveness. Currently, signatories to the Framework include only AT&T Mobility, CTIA, GCI, Southern Linc, T-Mobile, U.S. Cellular, and Verizon Wireless. Additionally, the Competitive Carriers Association filed a letter supporting the Framework. As the list of signatories demonstrates, there are a number of wireless providers who are not signatories to the Framework. Further, the Framework signatories only include wireless providers. Would greater participation in the Framework enhance its effectiveness? Are there steps the Commission can take to encourage voluntary participation beyond the scope of the existing signatories, such as to include smaller wireless providers, or entities beyond the mobile-wireless industry, such as facilities-based backhaul providers, covered 911 service providers, cable, wireline, broadcast, satellite, or interconnected VoIP providers? Should the Framework or portions of the Framework be expanded to include any other stakeholders or organizations?

17. *Improving Wireless Roaming.* The Framework commits its signatories to provide reasonable roaming in situations where: ''(i) A requesting carrier's network has become inoperable and the requesting carrier has taken all appropriate steps to attempt to restore its own network, and (ii) the home carrier has determined that roaming is technically feasible and will not adversely affect service to the home carrier's own subscribers,'' with such roaming arrangements ''limited in duration and contingent on the requesting carrier taking all possible steps to restore service on its own network as quickly as possible.'' *Framework Order,* 31 FCC at 13752–53, para 19.

18. Recent events suggest that roaming during disaster contexts can be improved. As the *Hurricane Michael Report* found, ''at least *some* wireless providers did not take advantage of the types of disaster-related roaming agreements envisioned in the Framework, allowing their customers to remain in the dark rather than roam on a competitor's network.'' FCC, Public Safety and Homeland Security Bureau, October 2018 Hurricane Michael's Impact on Communications: Preparation, Effect, and Recovery, PS Docket No. 18–339, Report and Recommendations at 6 (PSHSB 2019), *https://docs.fcc.gov/public/attachments/DOC-357387A1.pdf* (*Hurricane Michael Report*). During Hurricane Ida, there was limited transparency, and therefore understanding, regarding the status of roaming, including where it was available and where it was not, and which network technologies were utilized. We seek comment on how best to address these issues through the voluntary Framework. Are the current Framework pre-requisites to triggering disaster roaming too restrictive, to the detriment of consumers? In particular, we seek comment on improvements to the Framework to ensure roaming is operational prior to an event and seamless during emergencies—addressing both resiliency and restoration—such as annual testing of roaming capabilities and coordination processes. Are there other improvements that can be made to ensure that roaming is made available in a timely manner and for the benefit of the maximum population possible? For example, should there be minimum timeframes by which a provider must respond to a disaster roaming request? Are there conditions or other criteria that could be incorporated into the Framework to determine that, once met, roaming should be available automatically in qualifying disaster areas? If a roaming request is deemed technically infeasible, how should that determination be conveyed? What criteria should be used to determine whether roaming is technically feasible? Have there been instances where roaming requests have been unreasonably denied or responses to such requests have been unreasonably delayed, or where the roaming-related provisions of the Framework did not work as intended? During Hurricane Ida, we understand that initial requests for roaming under the Framework focused on access to 3G networks. Are there benefits to encouraging roaming access to newer generations of network technology and, if so, how can the Commission best support such arrangements? To what extent do capacity challenges or network configuration issues also hinder effective roaming, and how should any improvements to the Framework account for this concern? Should there be any improvement in the standards or their implementations to ensure the emergency roaming is automatically and seamlessly accessible to user devices without requiring any action from the user? Can providers' readiness to execute such disaster-triggered roaming be verified and tested? What are the public safety benefits and costs associated with these improvements in wireless roaming?

19. *Fostering Mutual Aid.* The Framework commits its signatories to foster mutual aid during disasters. Nevertheless, we observed prolonged outages during Hurricane Ida. We seek comment on how signatories fostered mutual aid, such as through sharing physical assets, during Hurricane Ida and other recent disasters, and how effective this mutual aid has been in ensuring continuity of communications. Are there instances in which reasonable requests for mutual aid were denied by wireless providers? Should the Framework do more to strengthen the effectiveness of mutual aid? What benefits would accrue if other segments of the communications industry—such as cable, wireline, and broadcast—agreed to foster mutual aid during disasters?

20. *Enhancing Municipal Preparedness and Restoration.* Framework signatories convened with local government representatives' public safety subject matter experts and developed best practices to facilitate coordination before, during, and after emergencies and disasters in order to maintain and restore wireless service continuity. Were these best practices

utilized in Hurricane Ida and other disasters, and how effective were these best practices in real-world conditions? Should they be updated in light of lessons learned from these disasters? Are there additional actions that wireless providers and other stakeholders (*e.g.,* backhaul service, wireline service providers) can take to ensure appropriate and effective coordination with local agencies to mitigate the impact of service disruptions? What are the respective costs and benefits? For example, should providers establish processes for sharing real-time restoration efforts? Should the Framework include coordination obligations and particular coordination activities or best practices? Are there are other steps that the Commission can take to improve coordination? The Commission also seeks comment on the recommendations of the Broadband Deployment Advisory Committee's Disaster Response and Recovery Working Group pertaining to coordination with local governments and building and maintaining formal relationships across industry and government stakeholders, and coordination and information sharing between stakeholders during the disaster planning and recovery phases.

21. *Increasing Local Preparedness and Consumer Readiness.* The Framework commits signatories to increase consumer readiness and preparation through the development and dissemination with consumer groups of a Consumer Readiness Checklist. Is there evidence that the public is aware of this checklist? How is it promoted? Are there other steps that wireless providers should take to foster local preparedness and consumer readiness in the face of natural disasters, such as public service announcements? What are the benefits and costs associated with those steps? Should the Commission explore additional consumer awareness and preparedness activities?

22. What measures are in place to ensure that information is accessible to all Americans? Consumer groups note that the deaf and hard-of-hearing communities often rely on multiple forms of communications before and during emergencies, and recommend that signatories work with these communities to ensure information is accessible. Should the Framework require signatories to conduct outreach through multiple forms of communication, such as public service announcements on television, radio, and social media that is accessible to both hard-of-hearing and non-English speaking communities? Verizon suggests providers can maintain a dedicated website for a specific disaster event. Should the Framework require signatories to meet with groups representing persons with disabilities to provide information on emergency planning and resources? Are there other steps the Commission should take to improve communications with these and other communities?

23. *Improving Public Awareness.* Finally, the Framework commits signatories to improve public awareness and stakeholder communications on service and restoration status, through sharing DIRS data on cell site outages on an aggregated, county-by-county basis in the relevant geographic area. Since the Framework was released, signatories have agreed to share additional data with the public, including more granular data on the cause of cell site outages and the number of in-service cell sites operating on backup power. The Commission has also requested comment on whether other outage data, *e.g.,* whether the service disruption extends to 911 service, should be disclosed to the public. *See* Amendments to Part 4 of the Commission's Rules Concerning Disruptions to Communications, et al., Third Notice of Proposed Rulemaking, FCC 21–45, 2021 WL 1603461, at *13–16, paras. 36–46 (Apr. 22, 2021). Would public disclosure of additional information regarding service disruptions promote public safety? If so, what additional information should be disclosed? What are the benefits and costs associated with releasing this information directly to the public? What mechanisms are in place in communities to impart awareness about recovery planning and long term-term resiliency, and are those mechanisms accessible to persons with disabilities? How might those mechanisms differ across communities or geographic areas, and how can those differences be accommodated by Framework signatories?

24. *Scope of Framework Obligations.* We seek comment on the scope of the Framework's obligations. Should we expand the scope of what is expected in the event of a disaster? What additional or revised measures are warranted to address gaps in promoting resiliency and what are their costs and benefits? For example, should the voluntary Framework include provisions regarding the placement of back-up systems, such as Cells on Light Trucks, so that they are ready to deploy for vulnerable infrastructure to improve service restoration time? Should the Framework include requirements for restoration or prioritization of text-to-911 capability in areas where the PSAP is text-capable, as text-to-911 can be an important communications solution in emergencies, particularly for individuals with disabilities? Should the Framework include provisions that address backhaul redundancy and resiliency? For example, could the Framework address a limit on the number of cell sites operating on a single backhaul fiber link? What other steps would promote backhaul resiliency during disasters?

25. *Framework-Related Reporting.* We seek comment on whether we should require wireless providers to submit reports to the Commission detailing implementation of the voluntary Framework in real time or in the aftermath of a disaster. What are the benefits and costs associated with such a reporting requirement? We seek comment on what information these reports should include, such as specific information related to the way the provider adhered to any roaming, mutual aid, consumer outreach, or related provisions of the Framework suggested above. For example, should the Commission be notified when roaming has been activated or refused, including information on which generational technologies it has been activated, and as to which providers are roaming on which networks? Should the Commission be notified when resources or services are shared through mutual aid? How soon after wireless provider action should such notifications be made and how should they be made?

26. *Codifying the Framework.* In response to our prior inquiries, some commenters have urged the Commission to reexamine the voluntary nature of the Framework. Some of these commenters highlight the Commission's *Hurricane Michael Report* to suggest that existing voluntary coordination efforts, including the Framework, may not be sufficient to promote wireless network resiliency and situational awareness during and immediately after emergencies. Accordingly, we seek comment on whether some or all of the existing or a modified Framework should be mandatory, and for whom. What are the costs and benefits of doing so? We also seek comment on our legal authority to mandate disaster-based obligations in line with the existing or an expanded Framework. Would the aggregate of these solutions address the failures highlighted by the *Hurricane Michael Report* or should additional measures be considered? Finally, we seek comment on how the Commission should enforce any mandatory obligations that are not met.

B. Promoting Situational Awareness During Disasters

27. Over the years, our experience has shown that DIRS and NORS are vital public safety tools that equip the Commission and its federal and local partners with actionable situational awareness information for identifying and resolving threats to 911 and other emergency service communications. DIRS focuses on infrastructure status information rather than service outage information, as in NORS. NORS thus draws a distinction between service outages that affect just 911 and other types of service outages. Currently, there is limited visibility on how disasters impact 911 service specifically. Requiring DIRS reporting in the event of disaster-related outages would help to close this information gap. *Amendments to Part 4 of the Commission's Rules Concerning Disruptions to Communications,* PS Docket No. 15–80, Second Report and Order, 36 FCC Rcd 6136, 6139, paras. 8, 9 (2021). DIRS broadly collects infrastructure status information about the nation's communications networks, but participation is voluntary for the nation's service providers. While DIRS is voluntary, the Commission recently required a subset of service providers that choose to accept Stage 2 funding from the Uniendo a Puerto Rico Fund or the Connect USVI Fund to report in DIRS when it is activated in their respective territories. *Puerto Rico & USVI USF Fund Report and Order,* 34 FCC Rcd at 9174, 9176–77, paras. 133, 138–140.

28. The Commission initially grounded its voluntary approach on observations that a voluntary paradigm worked well during Hurricane Katrina and that a mandatory reporting process would likely not be adaptable to unique aspects of each particular crisis. *Recommendations of the Independent Panel Reviewing the Impact of Hurricane Katrina on Communications Networks,* EB Docket No. 06–119 et al., Order, 22 FCC Rcd 10541, 10549, para. 22 (2007). Since that time, the Commission has observed that, while the nation's large providers typically elect to voluntarily report in DIRS, smaller providers often do not. This not only reduces the total number of DIRS filings available to inform the Commission's analysis of network reliability, but also reduces the Commission's situational awareness, including awareness of the state of 911 and other emergency services, in locations served by smaller providers, which are often vulnerable rural or other hard to access areas. This also creates ambiguity about whether a provider's lack of DIRS filings means that its network infrastructure actually remains undamaged, it is choosing not to voluntarily participate in DIRS, or it is unable to file, *e.g.,* because it cannot access DIRS due to disruption of its internet access.

29. Meanwhile, NORS participation is mandatory, but it is centered on disruptions to voice telephony. Under our rules, certain service providers—wireline, cable, satellite, wireless, interconnected VoIP, and Signaling System 7 providers—must submit outage reports to NORS for voice and other outages that exceed specified duration and magnitude thresholds. 47 CFR 4.9. Service providers are required to submit a preliminary notification within two hours after determining that an outage is reportable, followed by an initial outage report within three calendar days, and a final report no later than 30 days after discovering the outage. 47 CFR 4.9. These reports are intended to address ''the critical need for rapid, complete, and accurate information on service disruptions that could affect homeland security, public health or safety, and the economic well-being of our Nation . . . .'' *2004 Part 4 Report and Order,* 19 FCC Rcd at 16833, para. 1. The Bureau analyzes NORS data to assess the magnitude of major outages, identify trends, and promote network reliability. However, these outage reporting requirements do not collect information about disruptions specifically to broadband service. This means the Commission has limited situational awareness about outages involving broadband service.

30. We seek comment on steps the Commission can take to address these issues and encourage better situational awareness through DIRS and NORS. Starting with DIRS, are there steps the Commission can take to encourage broader voluntary participation during disasters, including from smaller providers? Alternatively, should the Commission consider requiring the nation's service providers, *i.e.,* cable providers, Direct Broadcast Satellite providers, Satellite Digital Audio Radio Service, TV and radio broadcasters, Commercial Mobile Radio Service and other wireless service providers, wireline providers, and VoIP providers, to report their infrastructure status information in DIRS when the Commission activates DIRS in geographic areas in which they broadcast or otherwise provide service? We recognize that a proposed requirement to file in DIRS must be balanced against additional burdens on service providers, particularly as DIRS reports are filed in the midst of disasters and other emergencies. If we were to explore requiring DIRS filing, we seek comment on our legal authority to do so, the costs and benefits associated with mandatory reporting, and how the Commission should enforce any failure to file DIRS information.

31. With respect to NORS, we seek comment on the public interest benefits and the costs of reporting of broadband service outages. Would such reporting likewise improve emergency managers' situational awareness during disasters? Or do public safety officials and others currently have access to broadband service outage data through other means? Could this data be leveraged to help identify broadband outage trends, and if so, how could this knowledge support first response and network reliability efforts?

32. We seek comment on suspension of NORS reporting requirements during disasters. Under our current voluntary DIRS reporting approach, the Bureau suspends NORS reporting obligations, via public notice, for providers who elect to report in DIRS for the duration of its activation period. Formally codifying this practice in our rules may give providers more clarity on their obligations and streamline and formalize existing practices. We therefore seek comment on whether to codify in our part 4 rules the Commission's typical practice of granting to providers a waiver of their NORS reporting requirements when they report the outage in DIRS. Are there needs of public safety officials or others that are not being met by the current reporting practices? If so, will such gaps remain when our NORS and DIRS information sharing rules become effective? *Amendments to Part 4 of the Commission's Rules Concerning Disruptions to Communications,* PS Docket No. 15–80, Second Report and Order, 36 FCC Rcd 6136 (2021).

33. We note that there may be instances in which DIRS is deactivated but some providers have not yet fully restored service, resulting in limited continuing outages. In these instances, the Commission no longer has situational awareness as to the status of those providers' services, because updates are no longer being filed in DIRS and the outage was never filed in NORS. We seek comment on how to best address this gap and ensure that the Commission maintains situational awareness of outages. Should providers with ongoing outages at the time of DIRS deactivation be required to report those outages in NORS?

34. In light of the concerns noted above, we also seek comment on steps

the Commission can take to increase its situational awareness of the state of 911 and other emergency services.

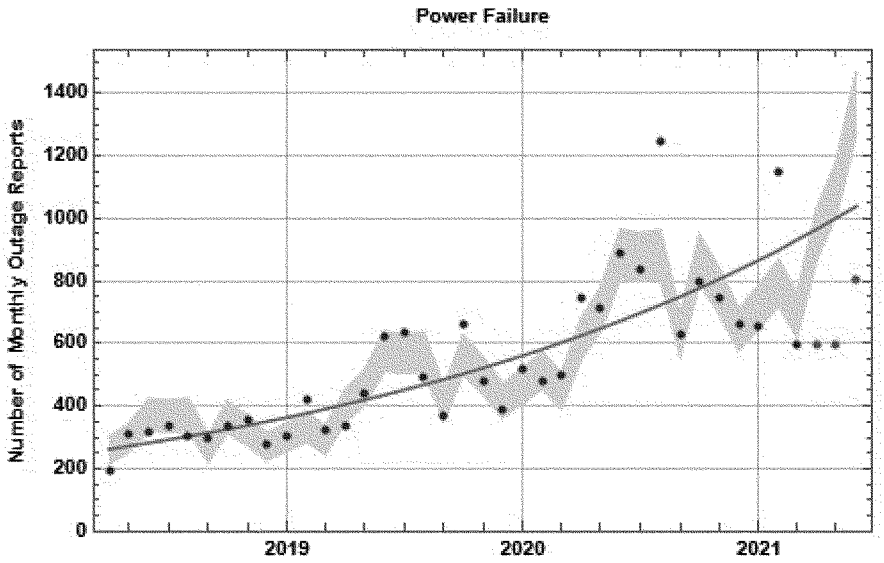
C. Addressing Power Outages

35. The recent devastation wrought by Hurricane Ida, which left hundreds of thousands of Louisianans without power, water, and other basic utilities, also extended to the region's communications infrastructure. Data compiled by the Commission shows that approximately half of all cellular sites in New Orleans and the surrounding disaster area remained out of service nearly two days after the worst effects of Ida had passed, with no clear timetable for the restoration of these networks. NORS and DIRS data collected by the Commission in the aftermath of Hurricane Ida and other recent disaster events reveal that a lack of commercial power at key equipment and facilities is the single biggest reason why communications networks transmitting 911 service and related emergency information fail in the aftermath of disaster events. For example, the Commission's DIRS data show that the majority of cell site outages in the immediate aftermath of Hurricane Ida's central disaster region were due to a lack of commercial power availability. Communications Status Report for Areas Impacted by Hurricane Ida at 5–6 (August 31, 2021), *https://docs.fcc.gov/public/attachments/DOC-375367A1.pdf.*

36. More generally, Commission analysis of DIRS data shows that over 50% of cell site outages that occurred during major 2020 earthquakes, hurricanes, and storms were due to power failures. The Commission's NORS outage data similarly reveal that the number of outages caused by power failures has been steadily increasing for the past several years and that power failures are currently driving a nationwide trend in the increase of outages. The Commission received 9,158 outage reports in 2020 alone for communications disruptions caused by power failures, potentially affecting 63,097,389 customers. Of those customers, 4.3 million potentially experienced service disruptions on a single day.

37. Without power to support providers' network operations in the aftermath of disasters, the public is unable to place potentially life-saving 911 calls, local emergency management officials are unable to transmit EAS and WEA messages, evacuation orders, and other public safety-related information, and first responders are unable to coordinate effectively to save lives and property. Conversely, with backup power in place, providers are able to bring their networks online and, if necessary, immediately begin diagnosing and addressing damage that their networks may have sustained.

38. Hurricane Ida thus continues an unfortunate (though potentially addressable) trend, demonstrating that the nation's communications infrastructure remains highly prone to failure due to disruptions to commercial power in the face of disasters. This reinforces observations that we have made during recent hurricane and wildfire seasons, earthquakes in Puerto Rico, and this year's severe winter storms in Texas. If the current trend continues without corrective action, the frequency of outages will worsen in coming years as the nation experiences disaster events of increasing severity, duration, and impact, including hurricanes, flooding, and wildfires.



NORS Data Trend in Outages Caused by Power Failure, April 2018 to June 2021

This figure depicts the number of monthly final outage reports in NORS with power failure as a reported cause over time. The red dots represent the numbers of outage reports in 2Q21 months and blue dots represent months prior to 2Q21. The green line shows the expected number of outages in each month without taking seasonality effects into account; as such, it represents the general overall trend in the three-year window immediately preceding 2Q21 (April 2018 through March 2021). The shaded gray area indicates a 99% confidence interval for each month. This confidence interval is defined by the expected number of outages in each month based on the trend and seasonality effects. These data do not include outages caused by power failures that were reported in DIRS. They also do not include outages that are not service affecting (*e.g.,* outages of transport facilities with diverse routes)

or special facility outages (outages of single circuits with Telecommunications Service Priority Level 1 or 2).

39. In view of this context, we now seek to explore communications resilience strategies for power outages. As part of this review, we seek to identify actions the Commission, communications providers, and power companies can cooperatively take to encourage and increase coordination in the power and communications sectors before, during, and after an emergency or disaster. We also seek to better understand how changing circumstances since the Commission's last broad consideration of backup power (including trends showing increasingly severe storms, wildfires, and other disasters, and advances in power technology) may bear on whether and how backup power or alternative measures may help promote continuity of power, including for PSAPs and emergency services. We seek comment on this issue.

40. As an initial matter, we seek comment on communications service provider coordination with power companies before, during, and after disasters, including efforts of the Cross-Sector Resiliency Forum. Are existing coordination efforts effective at minimizing communications service outages that are caused by power outages? Are there coordination activities that communications service provider and power companies could potentially take that have not yet been formalized or operationalized? If so, what steps could the Commission take to encourage this coordination? For example, should the Commission convene stakeholders from the electric industry, telecommunications sector, and public safety agencies to take part in regional coordination events to encourage greater cross-sector coordination in preparing for and in response to disasters? Should the Commission coordinate with gubernatorial offices and state emergency management agencies to encourage integrating communications providers and power companies into response planning, execution, and exercises?

41. Next, we seek comment on how backup power or alternative measures may help promote the continuity of service during or after disasters. We seek comment on the current state of providers' backup power implementations. For example, how many hours of backup power do providers typically maintain, what technologies do they use to meet their requirements, and how readily deployable are those technologies when needed? Does the amount or type of backup power solution differ depending upon the facility or type of infrastructure? What are the benefits and challenges of maintaining backup power on-site? If not maintained on-site, how could providers ensure that they can move backup power resources on-site with minimal delay when disaster strikes? What steps do providers take to adequately mitigate the risk that a disaster event that disrupts primary power would also knock out any on-site backup power resources (*e.g.,* fuel generators)? What types of backup power solutions are available for the various elements of infrastructure that may require it?

42. We seek comment on what steps service providers would need to take with respect to backup power deployment to significantly reduce the number of communications disruptions caused by power outages. How many hours of on-site backup power would be appropriate at their facilities to significantly reduce the frequency of power-related service disruptions? Are there events or geographic areas in which more hours of backup power are needed than others? To maximize the effectiveness of backup power solutions, should backup power be provisioned at certain critical points in communications infrastructure, and if so, at which points? In general, how should the Commission define or otherwise identify facilities and equipment that are critical to ensuring that emergency communications can be transmitted in the aftermath of a disaster? Are there differences across different types of communications networks or geographies where they are located that are relevant to deployment of backup power solutions or performance during power outages more generally? Is the deployment of on-site backup power sufficient to keep networks online in view of other potentially independent factors that may cause a network to fail during a disaster, *e.g.,* lack of hardened and resilient network equipment? If it is not sufficient, what other steps should service providers take to avoid service disruptions? What are the associated costs and benefits?

43. As we explore the potential for wider backup power implementation, we seek comment on service providers' experiences with any state-specific backup power requirements as well as the potential cost of implementation.

44. We also seek comment on any alternatives to on-site backup power that have also proven successful or have the potential to reduce the frequency, duration, or severity of disruptions to communications services caused by power outages. Are there other technical solutions for preventing service disruptions caused by power outages or other efforts to reduce the number of service disruptions that we have not raised here?

45. We also seek comment on the Commission's existing requirements for covered 911 service providers to implement reasonable central-office backup power measures to ensure 911 reliability. 47 CFR 9.19(b). The Commission adopted these and other requirements for covered 911 service providers to promote 911 network resiliency. 47 CFR 9.19. As noted above, Louisiana had three PSAPs offline due to damaged power and communications infrastructure in the aftermath of Hurricane Ida. Other PSAPs were also impacted as generators began to fail. Are there steps the Commission can take, such as revisions to our resiliency rules (*see, e.g.,* 47 CFR parts 4, 9) or encouraging of voluntary measures, to make it more likely that PSAPs will have the necessary resources to continue service during and after disasters? Are there other considerations pertaining to 911 outages and access to emergency services in the wake of a disaster?

46. *Digital Equity and Inclusion.* Finally, the Commission, as part of its continuing effort to advance digital equity for all, including people of color, persons with disabilities, persons who live in rural or Tribal areas, and others who are or have been historically underserved, marginalized, or adversely affected by persistent poverty or inequality, invites comment on any equity-related considerations and benefits (if any) that may be associated with the proposals and issues discussed herein. Specifically, we seek comment on how our proposals may promote or inhibit advances in diversity, equity, inclusion, and accessibility, as well the scope of the Commission's relevant legal authority.

IV. Procedural Matters

47. *Paperwork Reduction Act.* This document contains proposed new and modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the OMB to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4),

we seek specific comment on how we might further reduce the information collection burden for small business concerns with fewer than 25 employees.

48. *Ex Parte Rules—Permit-But-Disclose.* This proceeding shall be treated as ''permit-but-disclose'' proceedings in accordance with the Commission's ex parte rules. 47 CFR 1.1200–1.1216. Persons making ex parte presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral ex parte presentations are reminded that memoranda summarizing the presentation must: (1) List all persons attending or otherwise participating in the meeting at which the ex parte presentation was made; and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda, or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during ex parte meetings are deemed to be written ex parte presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written ex parte presentations and memoranda summarizing oral ex parte presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's ex parte rules.

49. *Regulatory Flexibility Act.* The Regulatory Flexibility Act of 1980, as amended (RFA), requires that a regulatory flexibility analysis be prepared for notice and comment rulemaking proceedings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' 5 U.S.C. 605(b). Accordingly, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) concerning potential rule and policy changes contained in this Notice of Proposed Rulemaking.

V. Legal Basis

50. Authority for the actions proposed in this Notice of Proposed Rulemaking may be found in sections 1, 4(i) through (j), 4(n) through (o), 201, 202, 214, 218, 251(e)(3), 254, 301, 303(b), 303(g), 303(r), 307, 309(a), 309(j), 316, 332 and 403, of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i) through (j), 154(n) through (o), 201, 202, 214, 218, 251(e)(3), 254, 301, 303(b), 303(g), 303(r), 307, 309(a), 309(j), 316, 332, 403; sections 2, 3(b), and 6 and 7 of the Wireless Communications and Public Safety Act of 1999, 47 U.S.C. 615 note, 615, 615a–1, 615b, section 106 of the Twenty First Century Communications and Video Accessibility Act of 2010, 47 U.S.C. 615c, and section 506(a) of the Repack Airways Yielding Better Access for Users of Modern Services Act of 2018 (RAY BAUM's Act).

VI. Initial Regulatory Flexibility Analysis

51. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in the Notice of Proposed Rulemaking in this proceeding. Written public comments are requested on this IRFA, including comments on any alternatives. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments as specified in the *NPRM.*

A. Need for, and Objectives of, the Proposed Rules

52. The *NPRM* proposes steps to safeguard and improve transmission of life-saving 911, Emergency Alert System (EAS), Wireless Emergency Alert (WEA) messages and other life-saving information during emergencies by improving the reliability, resiliency, and continuity of associated communications networks. More specifically, the Notice of Proposed Rulemaking:

- Considers whether elements of the Wireless Network Resiliency Cooperative Framework (Framework)—a voluntary agreement developed by the wireless industry in 2016 to provide mutual aid in the event of a disaster—could be improved to enhance the reliability of communication networks, including by inquiring into whether the public would benefit from codifying some or all of the Framework into the Commission's rules.
- Seeks comment on how the Commission can better promote situational awareness during disasters through its Disaster Information Reporting System (DIRS) and Network Outage Reporting System (NORS). (Henceforth, the term ''nation's service providers'' will refer collectively to this group of entities.).
- Explores communications resilience strategies to address one of the primary reasons for service disruptions: Electric power outages, including through an exploration of backup power implementations.

53. These proposals are made against the backdrop of Hurricane Ida, which hit the United States as a Category 4 hurricane in August 2021 and caused significant flooding and damage in several states along the southern and northeastern corridors of the United States. Hurricane Ida, as well as recent hurricane and wildfire seasons, earthquakes in Puerto Rico, and severe winter storms in Texas demonstrate that America's communications infrastructure remains susceptible to disruption during disasters. These disruptions can prevent the transmission of 911 calls, first responder communications, EAS and WEA messages, and other potentially life-saving information. They also can have cascading detrimental effects on the economy and other critical infrastructures due to interdependencies among sectors, including the transportation, medical, and financial sectors, among others. Importantly, these disruptions may involve any or all communications networks—including wireline, wireless, cable, satellite, or broadcast facilities.

B. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

54. The RFA directs agencies to provide a description of and, where feasible, and estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A small business concern is one that: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria

established by the Small Business Administration (SBA). Below is a list of such entities.

- Interconnected VoIP services;
- Wireline Providers;
- Wireless Providers—Fixed and Mobile;
- Satellite Service Providers; and
- Cable Service Providers.

C. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

55. We expect the potential rules in the *NPRM* will impose new or additional reporting or recordkeeping and/or other compliance obligations on service providers in the following ways:

- *Wireless Resiliency Framework.* Any providers that are required to participate in elements of the Framework who do not already do so, potentially including smaller wireless providers and entities beyond the mobile-wireless industry, such as facilities-based backhaul providers, covered 911 service providers, cable, wireline, broadcast, satellite, or interconnected VoIP providers would potentially need to keep records related to roaming agreements, mutual aid agreements, preparedness and restoration plans, improving consumer readiness and preparation and improving public awareness and stakeholder communications on service and restoration status. These providers would potentially have to submit reports to the Commission detailing implementation of the Framework in real time or in the aftermath of a disaster.
- *NORS and DIRS.* Any providers subject to DIRS reporting and new requirements related to NORS reporting, potentially including cable providers, Direct Broadcast Satellite providers, Satellite Digital Audio Radio Service, TV and radio broadcasters, Commercial Mobile Radio Service and other wireless service providers, wireline providers, VoIP providers, and broadband service providers, would report their communications outage information in NORS when their outages exceed thresholds specified in the Commission's Part 4 rules and infrastructure status information in DIRS when the Commission activates DIRS in geographic areas in which they broadcast or otherwise provide service.
- *Backup Power.* To the extent that the Commission were to adopt backup power requirements, any Public Safety Answering Points (PSAPs) or providers subject to them, potentially including cable providers, Direct Broadcast Satellite providers, Satellite Digital Audio Radio Service, TV and radio broadcasters, Commercial Mobile Radio Service and other wireless service providers, wireline providers, and VoIP providers, could potentially be required to take steps to make their networks more resilient to power outages, as discussed in the NPRM.

56. The NPRM seeks comment on a number of aspects of these proposals, including which providers should be subject to them, the public safety benefits and costs associated with a provider's implementation of the Framework, DIRS and NORS reporting, and backup power resiliency improvements. Given that these elements are currently unknown pending comment, the Commission is presently unable to quantify the costs of compliance with rules associated with these proposals, and whether small entities will need to hire professionals to comply. However, given that each proposal would make more reliable the transmission of 911 calls, first responder communications, EAS and WEA messages, and other potentially life-saving information, we tentatively conclude that the benefits exceed the costs of implementing any of these proposals. We seek comment on this tentative conclusion and urge commenters to provide detailed information in support of their comments.

D. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

57. None.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2021–23811 Filed 11–4–21; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 86, No. 212
Friday, November 5, 2021

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Farm Service Agency

[Docket ID FSA–2021–0010]

Notice of Funds Availability (NOFA) for the Organic and Transitional Education and Certification Program (OTECP)

AGENCY: Farm Service Agency, Department of Agriculture (USDA).

ACTION: Notification of funds availability.

SUMMARY: The Farm Service Agency (FSA) is announcing the availability of $20 million through the new Organic and Transitional Education and Certification Program (OTECP) for certified operations and transitional operations that incurred eligible expenses in fiscal years (FY) 2020, 2021, and 2022. Producers and handlers incur significant costs to obtain or renew USDA organic certification each year, and the economic challenges due to the COVID–19 pandemic have made obtaining and renewing USDA organic certification financially challenging for many operations. In this document, FSA is providing the eligibility requirements, application process, and payment calculation for OTECP.

DATES: *Funding availability:* Implementation will begin November 8, 2021.

Comment date: We will consider comments on the Paperwork Reduction Act that we receive by: January 4, 2022.

ADDRESSES: We invite you to submit comments on the information collection request. You may submit comments by the following methods, although FSA prefers that you submit comments electronically through the Federal eRulemaking Portal:

- *Federal eRulemaking Portal:* Go to: *www.regulations.gov* and search for Docket ID FSA–2021–0010. Follow the online instructions for submitting comments.
- *Mail, Hand-Delivery, or Courier:* Director, Safety Net Division, FSA, USDA, 1400 Independence Avenue SW, Stop 0510, Washington, DC 20250–0522. In your comment, specify the docket ID FSA–2021–0010.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

All comments received will be posted and publicly available on *https://www.regulations.gov.* Copies of the information collection may be requested by contacting the above address.

FOR FURTHER INFORMATION CONTACT: Kimberly Graham, telephone: (202) 720–7641; or by email: *kimberly.graham@usda.gov.* Persons with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice).

SUPPLEMENTARY INFORMATION:

Background

Producers and handlers of agricultural products that are organic operations are those that have obtained USDA organic certification under the USDA Agricultural Marketing Service (AMS) National Organic Program (NOP) established under the Organic Foods Production Act of 1990 (7 U.S.C. 6501–6524) and the USDA organic regulations in 7 CFR part 205. Organic operations are also required to receive continuation of certification to the USDA organic regulations. Farming operations (crop and livestock producers) that are transitioning to organic production methods prior to obtaining USDA organic certification are referred to in this document as transitional operations.

As part of the assistance that USDA is providing through the Coronavirus Aid, Relief, and Economic Security Act (CARES Act; Division B, Title I, Pub. L. 116–136), FSA is announcing the availability of $20 million through the new OTECP for certified operations and transitional operations that incurred eligible expenses in FY 2020, 2021, and 2022. Producers and handlers incur significant costs to obtain or renew USDA organic certification each year, and the economic challenges due to the COVID–19 pandemic have made obtaining and renewing USDA organic certification financially challenging for many operations. In this document, FSA is providing the eligibility requirements, application process, and payment calculation for OTECP.

OTECP will provide assistance to certified operations, as well as operations that are transitioning to organic production methods in anticipation of obtaining USDA organic certification. During the COVID–19 pandemic, these operations faced challenges due to loss of markets, increased costs, and labor shortages, in addition to costs related to obtaining or renewing their USDA organic certification, which producers and handlers of conventionally produced commodities do not incur. Transitional operations also faced the financial challenge of implementing practices required to obtain USDA organic certification without being able to obtain the premium prices associated with certified organic commodities. Further, for organic operations requesting an addition or update to their existing certification, the new land or facility must quickly move through the certification process, which typically includes an on-site inspection. Certified organic products must also meet very specific packaging and labeling requirements. Overall, this leads to reduced flexibility and unique supply chain challenges for organic businesses and farms when on-site inspections are not possible, as has often been the case during the COVID–19 pandemic.

Certified operations and transitional operations may apply for OTECP for eligible expenses paid during FY 2020, 2021, and 2022. OTECP covers 25 percent of a certified operation's eligible certification costs, up to $250 per certification category (crop, livestock, wild crop, handling, and State Organic Program fee).[1] It also covers 75 percent

[1] The USDA organic regulations recognize four separate categories that must be individually inspected for USDA organic certification: crop, livestock, wild crop, and handling (that is, processing). For the purpose of OTECP, State organic program fees are recognized as an additional category; these fees may be required by States that have established a State organic program according to 7 CFR 205.620 through 205.622, and are in addition to the costs of USDA organic certification under the four categories of USDA organic certification. A single operation may be certified under multiple categories. For example, a certified organic vegetable farm that also has certified organic chickens and produces certified organic jams would be required to be certified for three categories: crop, livestock, and handling.

of a transitional operation's eligible costs, up to $750, for each year. For both certified operations and transitional operations, OTECP covers 75 percent, up to $200, per year for registration fees for educational events that include content related to organic production and handling in order to assist operations in increasing their knowledge of production and marketing practices that can improve their operations, increase resilience, and expand available marketing opportunities. For both certified operations and transitional operations, OTECP also covers 75 percent, up to $100, of the cost of soil testing required under the NOP to document micronutrient deficiency.

Definitions

For this NOFA, the following definitions apply:

Certified operation means a crop or livestock production, wild crop harvesting, or handling operation, or portion of such operation, that is certified by an accredited certifying agent as utilizing a system of organic production or handling as described by the Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501–6524) and the regulations in 7 CFR part 205.

Educational event means an event, such as a conference, training program, or workshop, that provides educational content addressing topics related to organic production and handling, such as farming and production methods, NOP requirements, and marketing. It includes both in-person and remote events.

Soil testing means soil tests to document micronutrient deficiency as required by 7 CFR 205.601(j)(7).

Transitional operation means a crop or livestock production operation that is transitioning to organic production in anticipation of obtaining USDA organic certification, and that has an organic system plan or written documentation from a certifying agent accredited by the National Organic Program.

USDA organic certification means a determination made by a certifying agent that a production or handling operation is in compliance with the Organic Foods Production Act of 1990 (7 U.S.C. 6501–6524) and the regulations in 7 CFR part 205, which is documented by a certificate of organic operation.

The following definitions in 7 CFR 205.2 also apply to this NOFA: ''certification or certified,'' ''certifying agent,'' ''crop,'' ''handler,'' ''inspection,'' ''inspector,'' ''labeling,'' ''livestock,'' ''National Organic Program (NOP),'' ''organic,'' ''organic production,'' ''organic system plan,'' ''processing,'' ''producer,'' ''State organic program,'' and ''wild crop.''

Eligible Applicants

To be eligible for OTECP, an applicant must have paid eligible costs during FY 2020, 2021, or 2022 and, at the time of application, be either a certified operation or a transitional operation.

Operations with suspended, revoked, denied, or withdrawn USDA organic certifications at the time of application are ineligible for OTECP. OTECP is open to certified operations and transitional operations located in the 50 United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the U.S. Virgin Islands, and the Commonwealth of the Northern Mariana Islands.

Eligible and Ineligible Expenses

OTECP provides assistance for eligible expenses paid by the applicant during:

- FY 2020 (October 1, 2019, through September 30, 2020),
- FY 2021 (October 1, 2020, through September 30, 2021), and
- FY 2022 (October 2, 2021 through September 30, 2022).

Expenses that have been incurred by the applicant, but have not been paid, are not eligible for assistance through OTECP.

Certified operations may receive assistance for the following costs for obtaining or renewing their USDA organic certification for the crop, livestock, wild crop, handling, and State organic program categories:

- Application fees;
- Inspection fees, including travel costs and per diem for organic inspectors;
- USDA organic certification costs, including certification fees necessary to access international markets with which AMS has equivalency agreements or arrangements;
- State organic program fees;
- User fees or certifier sales assessments; and
- Postage.

For transitional crop and livestock operations, eligible expenses include fees charged by a certifying agent or consultant for pre-certification inspections and development of an organic system plan. Operations that incur eligible costs prior to USDA organic certification but became certified prior to the end of the fiscal year may not receive cost share for the same expense as both a certified and a transitional operation.

For both certified operations and transitional operations, soil testing and educational event registration fees are also eligible expenses.

The following expenses are not eligible for cost share under OTECP:

- Inspections due to violations of USDA organic regulations, or State organic program requirements;
- Costs related to non-USDA organic certifications;
- Costs related to any other labeling program;
- Materials, supplies, & equipment;
- Late fees;
- Membership fees;
- Consultant fees, except as described above for transitional operations;
- Costs related to educational event attendance other than registration fees; and
- Costs for tests other than soil testing as defined in this NOFA.

Application Process

The application period for 2020 and 2021 begins on November 8, 2021, and ends on January 7, 2022. The application period for 2022 will be announced next year. Applicants may apply for OTECP at any USDA Service Center.[2] Each applicant must submit a complete application in person or by mail, email, facsimile, or other methods announced by FSA. A complete application includes the following documentation:

- Form FSA–883, Organic and Transitional Education and Certification Program (OTECP), which includes a certification of the applicant's status as a certified operation or transitional operation and their eligible expenses;
- AD–2047, Customer Data Worksheet, if not already on file with FSA; and
- SF–3881, ACH Vendor/Miscellaneous Payment Enrollment Form, if not already on file with FSA.

Applicants may be required to provide additional documentation to FSA, if necessary, to verify eligibility or issue payment. Eligible expenses are based on applicant certification and are subject to spot check. In the event that an application must be verified, certified operations that previously applied for the Organic Certification Cost Share Program (OCCSP) through an FSA local office and provided documentation of eligible expenses are not required to resubmit that documentation to FSA; however, those applicants must submit documentation of any additional eligible expenses included on their OTECP application that were not previously included in

[2] USDA Service Center locations and contact information are available at *https://offices.sc.egov.usda.gov/locator/app.*

their OCCSP application. Certified operations that previously applied for OCCSP through a participating State Agency must submit the required documentation of their eligible expenses if requested by FSA.

Payments

OTECP payments are calculated separately for each category of eligible costs based on the percentage and maximum payment amounts in the following table.

Eligible applicants	Category of eligible expenses	Payment amount of eligible costs per category
Certified operations	Organic certification—crops	25 percent, up to $250.
	Organic certification—livestock	25 percent, up to $250.
	Organic certification—wild crop	25 percent, up to $250.
	Organic certification—handling	25 percent, up to $250.
	State Organic Program fees	25 percent, up to $250.
Transitional operations	Eligible transitional expenses	75 percent, up to $750.
Certified operations and transitional operations	Educational event registration fees	75 percent, up to $200.
	Soil testing	75 percent, up to $100.

Payments will be equal to the applicant's eligible expenses multiplied by the percentage for the applicable category in the table above, not to exceed the maximum payment amount for the category. An applicant must report any previous cost share assistance, excluding OCCSP payments, received for the expenses included on their application. For each crop, livestock, wild crop, handling, and State organic program fees category, the OTECP payment plus the additional cost share assistance, excluding OCCSP, cannot exceed the portion of the costs not covered by OCCSP.[3] For transitional expenses, soil testing, and educational event registration fees, the amount of the applicant's OTECP payment plus the reported additional cost share assistance cannot exceed 100 percent of the total amount of eligible expenses, as determined by FSA.

FSA will issue payments after the end of the application period for each fiscal year. If calculated payments exceed the amount of available funding, payments will be prorated.

Other Provisions

Participants are required to retain documentation in support of their application for 3 years after the date of approval. Participants receiving OTECP payments or any other person who furnishes such information to USDA must permit authorized representatives of USDA or the Government Accountability Office, during regular business hours, to enter the operation and to inspect, examine, and to allow representatives to make copies of books, records, or other items for the purpose of confirming the accuracy of the information provided by the participant.

If an applicant files an application with an FSA county office after the application deadline, the application will be considered a request to waive the deadline. The FSA Deputy Administrator for Farm Programs (Deputy Administrator) has the discretion and authority to consider the application and waive or modify application deadlines and other requirements or OTECP provisions not specified in law, in cases where the Deputy Administrator determines it is equitable to do so and where the Deputy Administrator finds that the lateness or failure to meet such other requirements or OTECP provisions do not adversely affect the operation of OTECP. Although applicants have a right to a decision on whether they filed applications by the deadline or not, applicants have no right to a decision in response to a request to waive or modify deadlines or program provisions. The Deputy Administrator's refusal to exercise discretion to consider the request will not be considered an adverse decision and is, by itself, not appealable.

Equitable relief and finality provisions specified in 7 CFR part 718, subpart D, apply to determinations under OTECP. Persons and legal entities who file an application with FSA have the right to an administrative review of any FSA adverse decision with respect to the application under the appeals procedures at 7 CFR parts 780 and 11. The determination of matters of general applicability that are not in response to, or result from, an individual set of facts in an individual participant's application for payment are not matters that can be appealed. Such matters of general applicability include, but are not limited to, the determination of eligible categories of expenses and payment rates.

Any payment under OTECP will be made without regard to questions of title under State law and without regard to any claim or lien. The regulations governing offsets in 7 CFR part 3 do not apply to payments made under this part.

In either applying for or participating in OTECP, or both, the applicant is subject to laws against perjury and any penalties and prosecution resulting therefrom, with such laws including but not limited to 18 U.S.C. 1621.

For the purposes of the effect of a lien on eligibility for Federal grants, loans, or programs (28 U.S.C. 3201(e)), USDA waives the restriction on receipt of funds under OTECP, but only as to beneficiaries who, as a condition of the waiver, agree to apply the OTECP payments to reduce the amount of the judgment lien.

In addition to any other Federal laws that apply to OTECP, the following laws apply: 18 U.S.C. 286, 287, 371, and 1001.

Paperwork Reduction Act Requirements

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), FSA is requesting comments from interested individuals and organizations on the information collection request associated with OTECP. The OTECP information collection request is for the producer and handler to provide FSA the information of their status of either a certified operation or transitional operation and their eligible expenses to qualify for the payments. FSA submitted

[3] OCCSP provides up to 75 percent of the costs incurred by a certified operation in obtaining USDA organic certification, up to a maximum of $750 (7 U.S.C. 6523), per category for crop, livestock, wild crop, handling, and State organic program fees. On August 10, 2020, FSA announced that the maximum OCCSP payment for FY 2020 through FY 2023 would be 50 percent of the certified organic operation's eligible costs, up to a maximum of $500 per certification category, due to the limited amount of funding available (85 FR 48149–48150). OTECP provides assistance for the portion of eligible USDA organic certification costs that is not covered by OCCSP. Prior participation in OCCSP is not required for certified operations to be eligible for OTECP. Certified operations that did not apply for OCCSP prior to the applicable program deadline may contact their local FSA office for information on how to submit a late-filed OCCSP application.

the emergency approval request that covers OTECP information collection activities to OMB for a 6-month approval. After the 60-day comment period ends, the information collection request will be submitted to OMB for a 3-year OMB approval.

Title: Organic and Transitional Education and Certification Program (OTECP).

OMB Control Number: 0560–New.

Type of Request: New Collection.

Abstract: The information collection request is required for the producers and handlers to provide their status as either a certified operation or transitional operation and their eligible expenses to get the OTECP payments. The forms for the producers and handlers to complete for the OTECP payments and the payment calculations are described in this document.

For the following estimated total annual burden on respondents, the formula used to calculate the total burden hour is the estimated average time per response multiplied by the estimated total annual responses. Public reporting burden for this information collection is estimated to include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collections of information.

Type of Respondents: Producer and handler.

Estimated Annual Number or Respondents: 13,250.

Estimated Number of Responses per Respondent: 1.69.

Estimated Total Annual Responses: 22,450.

Estimated Average Time per Response: 1 hour.

Estimated Total Annual Burden on Respondents: 22,450.

FSA is requesting comments on all aspects of this information collection to help us to:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of FSA, including whether the information will have practical utility;

(2) Evaluate the accuracy of the FSA's estimate of burden including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this document, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission for Office of Management and Budget approval.

Environmental Review

The environmental impacts of this final rule have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321–4347), the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and the FSA regulations for compliance with NEPA (7 CFR part 799).

The purpose of OTECP is to provide assistance to certified operations and transitional operations for the costs of obtaining and renewing USDA organic certification, and for eligible precertification and education costs, as well as soil testing. The Categorical Exclusions in 7 CFR 799.31 apply, specifically 7 CFR 799.31(b)(6)(iii) (that is, financial assistance to supplement income. . .). No Extraordinary Circumstances (7 CFR 799.33) exist. FSA has determined that this final rule does not constitute a major Federal action that would significantly affect the quality of the human environment, individually or cumulatively. Therefore, FSA will not prepare an environmental assessment or environmental impact statement for this regulatory action.

Catalog of Federal Domestic Assistance

The title and number of the Federal assistance program in the Catalog of Federal Domestic Assistance to which this NOFA applies is 10.139, Organic and Transitional Education and Certification Program (OTECP).

USDA Non-Discrimination Policy

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

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

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint* and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410 or email: *OAC@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

Zach Ducheneaux,

Administrator, Farm Service Agency.

[FR Doc. 2021–24384 Filed 11–4–21; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

[Docket No. RHS–21–Admin–0022]

Notice of Request for Approval of a New Information Collection

AGENCY: Rural Housing Service, Rural Business-Cooperative Service, and Rural Utilities Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Rural Business-Cooperative Service, Rural Housing Service, and the Rural Utilities Service, agencies of the Rural Development mission area within the U.S. Department of Agriculture (USDA), hereinafter collectively referred to as the Agency to request approval for a new information collection in support of compliance with applicable acts for planning and performing construction and other development work.

DATES: Comments on this notice must be received by January 4, 2022.

ADDRESSES: Comments may be submitted by the following method:

• *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.

FOR FURTHER INFORMATION CONTACT: Lynn Gilbert, Rural Development Innovation Center—Regulations Management Division, USDA, 1400 Independence Avenue SW, South Building, Washington, DC 20250–1522. Telephone: (202) 690–2682. Email *lynn.gilbert@usda.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that Rural Development is submitting to OMB for a new collection.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) The accuracy of the Agency's estimate of the burden of the proposed collection of information 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 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 may be sent by the Federal eRulemaking Portal: Go to *http://www.regulations.gov* and, in the lower ''Search Regulations and Federal Actions'' box, select ''RHS'' from the agency drop-down menu, then click on ''Submit.'' In the Docket ID column, select RHS–21-Admin-0022 to submit or view public comments and to view supporting and related materials available electronically. Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.

Title: 7 CFR 1901—Common Forms Package for Civil Rights Forms

OMB Number: 0575–New.

Expiration Date of Approval: Three years from approval date.

Type of Request: New information collection.

Abstract: The information collection under OMB Number 0575-New will enable the Agencies to effectively monitor a recipient's compliance with the civil rights laws, and to determine whether or not service and benefits are being provided to beneficiaries on an equal opportunity basis.

The Agencies are required to provide Federal financial assistance through its housing and community and business programs on an equal opportunity basis. The laws implemented in 7 CFR part 1901, subpart E, require the recipients of RD Federal financial assistance to collect various types of information, including information on participants in certain of these agencies' programs, by race, color, and national origin.

The information collected and maintained by the recipients of certain programs in RD are used internally by the agency for monitoring compliance with the civil rights laws and regulations. This information is made available to USDA officials, officials of other Federal agencies, and to Congress for reporting purposes. Without the required information, RD and its recipients will lack the necessary documentation to demonstrate that their programs are being administered in a nondiscriminatory manner, and in full compliance with the civil rights laws. In addition, the Agency and their recipients would be vulnerable in lawsuits alleging discrimination in the affected programs of these agencies, and would be without appropriate data and documentation to defend themselves by demonstrating that services and benefits are being provided to beneficiaries on an equal opportunity basis.

Estimate of Burden: RD is requesting approval for one respondent and a one-hour place holder in order for OMB to issue a control number for these forms. The burden for each of the forms will be accounted for within the individual Rural Development program collection packages using the form(s).

Respondents: Recipients of Rural Development Federal financial assistance, loan, and loan guarantee programs.

ESTIMATED NUMBER OF RESPONSES PER RESPONDENT PER FORM IN PACKAGE

Form No.	Responses per respondent
400–1, 4, 6	1

Comments from interested parties are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) 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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Chadwick Parker,

Acting Administrator, Rural Housing Service.

[FR Doc. 2021–24149 Filed 11–4–21; 8:45 am]

BILLING CODE 3410–XV–P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

[Docket No. RHS–21–Admin–0021]

Notice of Request for Approval of a New Information Collection

AGENCY: Rural Housing Service, Rural Business-Cooperative Service, and Rural Utilities Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Rural Business-Cooperative Service, Rural Housing Service, and the Rural Utilities Service, agencies of the Rural Development mission area within the U.S. Department of Agriculture (USDA), hereinafter collectively referred to as the Agency to request approval for a new information collection in support of compliance with applicable acts for planning and performing construction and other development work.

DATES: Comments on this notice must be received by January 4, 2022.

ADDRESSES: Comments may be submitted by the following method:

• *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.

FOR FURTHER INFORMATION CONTACT: Lynn Gilbert, Rural Development Innovation Center—Regulations Management Division, USDA, 1400 Independence Avenue SW, South Building, Washington, DC 20250–1522. Telephone: (202) 690–2682. Email *lynn.gilbert@usda.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that Rural Development is submitting to OMB for a new collection.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) The accuracy of the Agency's estimate of the burden of the proposed collection of information 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 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 may be sent by the Federal eRulemaking Portal: Go to *http://www.regulations.gov* and, in the lower ''Search Regulations and Federal Actions'' box, select ''RHS'' from the agency drop-down menu, then click on ''Submit.'' In the Docket ID column, select RHS–21-Admin-0021 to submit or view public comments and to view supporting and related materials available electronically. Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.

Title: 7 CFR 1927—Common Forms Package for Real Estate Title Clearance and Loan Closing.

OMB Number: 0575–New.

Expiration Date of Approval: Three years from approval date.

Type of Request: New information collection.

Abstract: The information collection under OMB Number 0575-New will enable the Agencies to effectively extend financial assistance to construct, improve, alter, repair, replace or rehabilitate dwellings, farm buildings, and/or related facilities to provide decent, safe, and sanitary living conditions and adequate farm buildings and other structures in rural areas. Title clearance is required to assure the Agency (s) that the loan is legally secured and has the required lien priority.

RD will be collecting information to assure that those participating in this program remain eligible to proceed with loan closing and to ensure that loans are made with Federal funds are legally secured. The respondents are individuals or households, businesses and non-profit institutions. The information required is used by the USDA personnel to verify that the required lien position has been obtained. The information is collected at the field office responsible for processing a loan application through loan closing. The information is also used to ensure the program is administered in manner consistent with legislative and administrative requirements. If not collected, the Agency would be unable to determine if the loan is adequately and legally secure. RD continually strives to ensure that information collection burden is kept to a minimum.

Information for the RD forms and their usage in this collection package are included in this supporting statement.

Estimate of Burden: RD is requesting approval for one respondent and a one-hour place holder in order for OMB to issue a control number for these forms. The burden for each of the forms will be accounted for within the individual Rural Development program collection packages using the form(s).

Respondents: Individuals or Households, Businesses, Closing agents/Attorneys and the field office staff.

ESTIMATED NUMBER OF RESPONSES PER RESPONDENT PER FORM IN PACKAGE

Form Nos.	Responses per respondent
1927–5, 8, 9, 10, 15, 19 and 20 ...	1
3550–25	1

Comments from interested parties are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) 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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Chadwick Parker,

Acting Administrator, Rural Housing Service.

[FR Doc. 2021–24150 Filed 11–4–21; 8:45 am]

BILLING CODE 3410–XV–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

[Docket No. RUS–21–ELECTRIC–0021]

Next Era Energy LLC, Notice of Availability of a Draft Environmental Impact Statement and Notice of Public Meeting; Correction

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice; correction.

SUMMARY: On October 4, 2021, the Rural Utilities Service (RUS), an agency of the United States Department of Agriculture (USDA), published a document announcing that a Draft Environmental Impact Statement (EIS) for a project proposed by Next Era Energy Inc (NEER), is available for public review and comment. RUS published the Draft EIS to inform interested parties and the general public about the project proposal and to invite the public to comment on the proposed action addressed in the Draft EIS. Following the publication of the Notice of Availability, the Agency found that a correction due to an error, is necessary. This correction changes the date public comments are due to RUS.

FOR FURTHER INFORMATION CONTACT: For information specific to this notice contact Kristen Bastis, Environmental Protection Specialist, Rural Utilities Service, Rural Development, USDA, 1400 Independence Avenue SW,

Washington, DC 20250–1522. Telephone: (202) 692–4910. Email *SkeletonCreekSolarPublicComments@usda.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2021–21506, appearing on page 54674 in the **Federal Register** of October 4, 2021, the following corrections are made:

Correction

On page 54674, in **DATES**, ''Written comments on this Draft EIS must be received by November 18, 2021'' is corrected to read as follows ''Written comments on this Draft EIS must be received by December 6, 2021''.

On page 54675, in **DATES**, ''For consideration in the final EIS, comments must be postmarked or received online by November 18, 2021'', is corrected to read as follows ''For consideration in the final EIS, comments must be postmarked or received online by December 6, 2021.''

Christopher A. McLean,

Acting Administrator, Rural Utilities Service, U.S. Department of Agriculture.

[FR Doc. 2021–24244 Filed 11–4–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Office of the Secretary

Membership of the Department Performance Review Board

AGENCY: Office of the Secretary, Department of Commerce.

ACTION: Notice of membership on the Department Performance Review Board.

SUMMARY: The Department of Commerce announces the appointment of those individuals who have been selected to serve as members of the Department Performance Review Board. The Department Performance Review Board is responsible for reviewing performance appraisals and ratings of select Senior Executive Service (SES) members. The appointment of these members to the Performance Review Board will be for a period of twenty-four (24) months.

DATES: The period of appointment for those individuals selected for the Department Performance Review Board begins on November 5, 2021.

FOR FURTHER INFORMATION CONTACT: Christine Covington, U.S. Department of Commerce, Office of Human Resources Management, Office of Executive Resources, 14th and Constitution Avenue NW, Room 50013, Washington, DC 20230, at (202)482–2613.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 4314 (c) (4), the Office of the Secretary, Department of Commerce (DOC), announces the appointment of those individuals who have been selected to serve as members of the Office of the Secretary Department Performance Review Board. The Department Performance Review Board is responsible for reviewing performance appraisals and ratings of select Senior Executive Service (SES) members. The appointment of these members to the Department Performance Review Board will be for a period of twenty-four (24) months.

The name and position title of each primary member of the Department Performance Review Board are set forth below:

Monica Gorman, Deputy Assistant Secretary for Manufacturing, International Trade Administration

Isabel Lisle Hannah, Director for Facilities and Environmental Quality, Office of the Secretary

Albert Fontenot, Associate Director for Decennial Census, U.S. Census Bureau

Benjamin Friedman, Deputy Under Secretary for Operations, National Oceanic and Atmospheric Administration

The name and position title of each alternate member of the Department Performance Review Board are set forth below:

Carol Rose, Chief Financial Officer and Director for Administration, Bureau of Industry and Security

Dennis Alvord, Deputy Assistant Secretary for Economic Development, Economic Development Administration

Dated: November 2, 2021

Christine Covington,

Human Resources Specialist, Office of Executive Resources, Office of Human Resources Management, Office of the Secretary, Department of Commerce.

[FR Doc. 2021–24241 Filed 11–4–21; 8:45 am]

BILLING CODE 3510–25–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

First Responder Network Authority

Public Combined Board and Board Committees Meeting

AGENCY: First Responder Network Authority (FirstNet Authority), National Telecommunications and Information Administration (NTIA), U.S. Department of Commerce.

ACTION: Announcement of meeting.

SUMMARY: The FirstNet Authority Board will convene an open public meeting of the Board and Board Committees.

DATES: November 17, 2021; 11:00 a.m. to 1:00 p.m. Eastern Standard Time (EST); Washington, DC.

ADDRESSES: The meeting will be held at the Park Hyatt Hotel located at 1201 24th Street NW, Washington, DC 20037. Due to restrictions on the number of people who can be present, members of the public will not be able to attend in-person but may listen to the meeting and view the presentation by visiting the URL: *https://stream2.sparkstreetdigital.com/20211117-firstnet.html.* If you experience technical difficulty, contact *support@sparkstreetdigital.com.* WebEx information can also be found on the FirstNet Authority website (*FirstNet.gov*).

FOR FURTHER INFORMATION CONTACT:

General information: Janell Smith, (202) 257–5929, *Janell.Smith@FirstNet.gov.*

Media inquiries: Ryan Oremland, (571) 665–6186, *Ryan.Oremland@FirstNet.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Middle Class Tax Relief and Job Creation Act of 2012 (codified at 47 U.S.C. 1401 *et seq.*) (Act) established the FirstNet Authority as an independent authority within NTIA. The Act directs the FirstNet Authority to ensure the building, deployment, and operation of a nationwide interoperable public safety broadband network. The FirstNet Authority Board is responsible for making strategic decisions regarding the operations of the FirstNet Authority.

Matters to be Considered: The FirstNet Authority will post a detailed agenda for the Combined Board and Board Committees Meeting on FirstNet.gov prior to the meeting. The agenda topics are subject to change. Please note that the subjects discussed by the Board and Board Committees may involve commercial or financial information that is privileged or confidential, or other legal matters affecting the FirstNet Authority. As such, the Board may, by majority vote, close the meeting only for the time necessary to preserve the confidentiality of such information, pursuant to 47 U.S.C. 1424(e)(2).

Other Information: The public Combined Board and Board Committees Meeting is accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Janell Smith at (202)

257–5929 or email: *Janell.Smith@FirstNet.gov* at least five (5) business days (November 10) before the meeting.

Records: The FirstNet Authority maintains records of all Board proceedings. Minutes of the Combined Board and Board Committees Meeting will be available on *FirstNet.gov.*

Dated: November 1, 2021.

Janell Smith,

Board Secretary, First Responder Network Authority.

[FR Doc. 2021–24128 Filed 11–4–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–028]

Hydrofluorocarbon Blends From the People's Republic of China: Final Results of the Expedited First Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this expedited sunset review, the Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on hydrofluorocarbon blends (HFC blends) from the People's Republic of China (China) would be likely to lead to the continuation or recurrence of dumping at the levels indicated in the ''Final Results of Review'' section of this notice.

DATES: Applicable November 5, 2021.

FOR FURTHER INFORMATION CONTACT: Jacob Garten or Benjamin A. Luberda, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3342 or (202) 482–2185, respectively.

SUPPLEMENTARY INFORMATION:

Background

On August 19, 2016, Commerce published the AD order on HFC blends from China.[1] On July 1, 2021, Commerce published the notice of initiation of the first sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On July 16, 2021, Commerce received notice of intent to participate within the 15-day deadline specified in 19 CFR 351.218(d)(1)(i) from the American HFC Coalition (Coalition), an association comprised of four U.S. producers of HFC blends: Arkema Inc.; The Chemours Company FC LLC; Honeywell International Inc.; and Mexichem Fluor Inc.[3] The individual members of the Coalition claimed interested party status under section 771(9)(C) as domestic producers and, collectively, under section 771(9)(E) of the Act as a trade or business association a majority of whose members manufacture, produce, or wholesale a domestic like product in the United States.[4]

On August 2, 2021, Commerce received adequate substantive responses to the notice of initiation from the Coalition within the 30-day deadline specified in 19 CFR 351.218(d)(3).[5] We received no substantive response from respondent interested parties with respect to the order covered by this sunset review.

On August 20, 2021, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties.[6] 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 *Order.*

Scope of the Order

The products subject to the *Order* are HFC blends. HFC blends covered by the scope are R–404A, a zeotropic mixture consisting of 52 percent 1,1,1-Trifluoroethane, 44 percent Pentafluoroethane, and 4 percent 1,1,1,2-Tetrafluoroethane; R–407A, a zeotropic mixture of 20 percent Difluoromethane, 40 percent Pentafluoroethane, and 40 percent 1,1,1,2-Tetrafluoroethane; R–407C, a zeotropic mixture of 23 percent Difluoromethane, 25 percent Pentafluoroethane, and 52 percent 1,1,1,2-Tetrafluoroethane; R–410A, a zeotropic mixture of 50 percent Difluoromethane and 50 percent Pentafluoroethane; and R–507A, an azeotropic mixture of 50 percent Pentafluoroethane and 50 percent 1,1,1-Trifluoroethane also known as R–507. The foregoing percentages are nominal percentages by weight. Actual percentages of single component refrigerants by weight may vary by plus or minus two percent points from the nominal percentage identified above.[7]

Any blend that includes an HFC component other than R–32, R–125, R–143a, or R–134a is excluded from the scope of the *Order.*

Excluded from the *Order* are blends of refrigerant chemicals that include products other than HFCs, such as blends including chlorofluorocarbons (CFCs), hydrochlorofluorocarbons (HCFCs), hydrocarbons (HCs), or hydrofluoroolefins (HFOs).

Also excluded from the *Order* are patented HFC blends, including, but not limited to, ISCEON® blends, including MO99TM (R–438A), MO79 (R–422A), MO59 (R–417A), MO49PlusTM (R–437A) and MO29TM (R–4 22D), Genetron® PerformaxTM LT (R–407F), Choice® R–421A, and Choice® R–421B.

HFC blends covered by the scope of the *Order* are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings 3824.78.0020 and 3824.78.0050. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope is dispositive.[8]

[1] *See Hydrofluorocarbon Blends from the People's Republic of China: Antidumping Duty Order,* 81 FR 55436 (August 19, 2016) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 86 FR 35070 (July 1, 2021).

[3] *See* Coalition's Letter, ''Five-Year (''Sunset'') Review of Antidumping Duty Order on Hydrofluorocarbon Blends and Components Thereof from China: Notice of Intent to Participate,'' dated July 16, 2021.

[4] *Id.* at 1.

[5] *See* Coalition's Letter, ''Hydrofluorocarbon Blends and Components Thereof from China: Substantive Response to Notice of Initiation of Five-Year (Sunset) Review of Antidumping Duty Order,'' dated August 2, 2021.

[6] *See* Commerce's Letter, ''Sunset Reviews Initiated for July 2021,'' dated August 20, 2021.

[7] R–404A is sold under various trade names, including Forane® 404A, Genetron® 404A, Solkane® 404A, Klea® 404A, and Suva®404A. R–407A is sold under various trade names, including Forane® 407A, Solkane® 407A, Klea®407A, and Suva®407A. R–407C is sold under various trade names, including Forane® 407C, Genetron® 407C, Solkane® 407C, Klea® 407C and Suva® 407C. R–410A is sold under various trade names, including EcoFluor R410, Forane® 410A, Genetron® R410A and AZ–20, Solkane® 410A, Klea® 410A, Suva® 410A, and Puron®. R–507A is sold under various trade names, including Forane® 507, Solkane® 507, Klea®507, Genetron®AZ–50, and Suva®507. R–32 is sold under various trade names, including Solkane®32, Forane®32, and Klea®32. R–125 is sold under various trade names, including Solkane®125, Klea®125, Genetron®125, and Forane®125. R–143a is sold under various trade names, including Solkane®143a, Genetron®143a, and Forane®125.

[8] *See Order.* Certain merchandise has been the subject of affirmative anti-circumvention determinations by Commerce, pursuant to section 781 of the Tariff Act of 1930, as amended (the Act). As a result, the circumventing merchandise is included in the scope of the *Order. See Hydrofluorocarbon Blends from the People's Republic of China: Final Negative Scope Ruling on Gujarat Fluorochemicals Ltd.'s R–410A Blend; Affirmative Final Determination of Circumvention of the Antidumping Duty Order by Indian Blends Containing Chinese Components,* 85 FR 61930 (October 1, 2020); *Hydrofluorocarbon Blends from the People's Republic of China: Final Scope Ruling on Unpatented R–421A; Affirmative Final Determination of Circumvention of the Antidumping Duty Order for Unpatented R–421A,* 85 FR 34416 (June 4, 2020); and *Hydrofluorocarbon Blends from the People's Republic of China: Affirmative Final Determination of Circumvention*

Analysis of Comments Received

All issues raised in this sunset review are addressed in the Issues and Decision Memorandum.[9] The issues discussed in the Issues and Decision Memorandum are the likelihood of continuation or recurrence of dumping and the magnitude of the dumping margin likely to prevail if the orders were revoked. 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.* A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Review

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to the continuation or recurrence of dumping at weighted-average dumping margins up to 285.73 percent.

Administrative Protective Order (APO)

This notice also serves as the only reminder to parties subject to an 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 orders is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing the final results and this notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218.

of the Antidumping Duty Order; Unfinished R–32/R–125 Blends, 85 FR 15428 (March 18, 2020).

[9] *See* Memorandum, ''Issues and Decision Memorandum for the Expedited First Sunset Review of the Antidumping Duty Order on Hydrofluorocarbon Blends from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Dated: October 29, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2021–24185 Filed 11–4–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) has received requests to conduct administrative reviews of various antidumping duty (AD) and countervailing duty (CVD) orders with September anniversary dates. In accordance with Commerce's regulations, we are initiating those administrative reviews.

DATES: Applicable November 5, 2021.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

SUPPLEMENTARY INFORMATION:

Background

Commerce has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various AD and CVD orders with September anniversary dates.

All deadlines for the submission of various types of information, certifications, or comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting time.

Notice of No Sales

If a producer or exporter named in this notice of initiation had no exports, sales, or entries during the period of review (POR), it must notify Commerce within 30 days of publication of this notice in the **Federal Register**. All submissions must be filed electronically at *https://access.trade.gov,* in accordance with 19 CFR 351.303.[1] Such submissions are subject to verification, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Further, in accordance with 19 CFR 351.303(f)(1)(i), a copy must be served on every party on Commerce's service list.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the POR. We intend to place the CBP data on the record within five days of publication of the initiation notice and to make our decision regarding respondent selection within 35 days of publication of the initiation **Federal Register** notice. Comments regarding the CBP data and respondent selection should be submitted within seven days after the placement of the CBP data on the record of this review. Parties wishing to submit rebuttal comments should submit those comments within five days after the deadline for the initial comments.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act, the following guidelines regarding collapsing of companies for purposes of respondent selection will apply. In general, Commerce has found that determinations concerning whether particular companies should be ''collapsed'' (*e.g.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless

[1] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

there has been a determination to collapse certain companies in a previous segment of this AD proceeding (*e.g.,* investigation, administrative review, new shipper review, or changed circumstances review). For any company subject to this review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value (Q&V) Questionnaire for purposes of respondent selection, in general, each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where Commerce considered collapsing that entity, complete Q&V data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that has requested a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of a particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[2] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial responses to section D of the questionnaire.

Separate Rates

In proceedings involving non-market economy (NME) countries, Commerce begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is Commerce's policy to assign all exporters of merchandise subject to an administrative review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, Commerce analyzes each entity exporting the subject merchandise. In accordance with the separate rates criteria, Commerce assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below. For these administrative reviews, in order to demonstrate separate rate eligibility, Commerce requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The Separate Rate Certification form will be available on Commerce's website at *https://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the certification, please follow the ''Instructions for Filing the Certification'' in the Separate Rate Certification. Separate Rate Certifications are due to Commerce no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding [3] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name,[4] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Application will be available on Commerce's website at *https://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Application, refer to the instructions contained in the application. Separate Rate Applications are due to Commerce no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

[2] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[3] Such entities include entities that have not participated in the proceeding, entities that were preliminarily granted a separate rate in any currently incomplete segment of the proceeding (*e.g.,* an ongoing administrative review, new shipper review, *etc.*) and entities that lost their separate rate in the most recently completed segment of the proceeding in which they participated.

[4] Only changes to the official company name, rather than trade names, need to be addressed via a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Certification.

Exporters and producers must file a timely Separate Rate Application or Certification if they want to be considered for respondent selection. Furthermore, exporters and producers who submit a Separate Rate Application or Certification and subsequently are selected as mandatory respondents will no longer be eligible for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents.

Initiation of Reviews

In accordance with 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following AD and CVD orders and findings. We intend to issue the final results of these reviews not later than September 30, 2022.

	Period to be reviewed
AD Proceedings	
India: Lined Paper Products, A–533–843	9/1/20–8/31/21
Cellpage Ventures Private Limited	
Dinakar Process Private Limited	
Goldenpalm Manufacturers PVT Limited	
ITC Limited-Education and Stationary Products Business	
JC Stationery (P) Ltd	
Kokuyo Riddhi Paper Products Pvt. Ltd.	
Lodha Offset Limited	
Lotus Global Private Limited	
M/s.Bhaskar Paper Products	
Magic International Pvt. Ltd.	
Marisa International	
Navneet Education Ltd.	
Pioneer Stationery Private Limited	
PP Bafna Ventures Private Limited	
SAB International	
SGM Paper Products	
Super Impex	
Italy: Certain Pasta, A–475–818	7/1/20–6/30/21
Pasta Castiglioni[5]	
Mexico: Emulsion Styrene-Butadiene Rubber, A–201–848	9/1/20–8/31/21
Industrias Negromex, S.A. de C.V.[6]	
Mexico: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes, A–201–847	9/1/20–8/31/21
Maquilacero S.A. de C.V.	
Productos Laminados de Monterrey S.A. de C.V.	
Republic of Korea: Cold-Rolled Steel Flat Products, A–580–881	9/1/20–8/31/21
Hyundai Steel Company	
KG Dongbu Steel Co., Ltd.	
POSCO	
POSCO International Corporation	
Republic of Korea: Heavy Walled Rectangular Welded Carbon Pipes and Tubes, A–580–880	9/1/20–8/31/21
HiSteel Co., Ltd.	
Dong-A-Steel Co., Ltd.	
SeAH Steel Corporation	
Republic of Korea: Oil Country Tubular Goods, A–580–870	9/1/20–8/31/21
AJU Besteel Co., Ltd.	
BS Metal Co., Ltd.	
Dong-A Steel Co., Ltd.	
Hansol Metal Co. Ltd.	
HiSteel Co., Ltd.	
Husteel Co., Ltd.	
Hyundai RB Co. Ltd.	
Hyundai Steel Company	
ILJIN Steel Corporation	
JORD C/O Youngkang., Ltd.	
K Steel Corporation	
Kukje Steel Co., Ltd.	
Kumkang Kind Co., Ltd.	
Master Steel Corp.	
MSTEEL Co., Ltd.	
NEXTEEL Co. Ltd.	
Nissei Trading Co., Ltd	
POSCO International Corporation	
Samsung P & J System	
SeAH Steel Corporation	
SeAH Coated Metal Corporation	

[5] Pasta Castiglioni's name was inadvertently misspelled in the initiation notice that published on September 7, 2021 (86 FR 50034). The company's name is corrected in this notice.

[6] The review requests referenced a second company, Dynasol LLC, which is Negromex's affiliated U.S. importer.

[7] Commerce inadvertently initiated an administrative review of Unicom Fasteners Co., Ltd. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 50034 (September 7, 2021). The correct company name is Unicorn Fasteners Co., Ltd.

[8] CS Wind Vietnam Co., Ltd.'s name was inadvertently misspelled in the initiation notice that published on October 7, 2021 (86 FR 55811). The company's name is corrected in this notice.

	Period to be reviewed
Steel-A Co. Ltd.	
Sung Won Steel Co., Ltd.	
TGS Pipe Co. Ltd.	
TJ Glovsteel Co. Ltd.	
Yuhwa Pipe Co. Ltd.	
Sultanate of Oman: Polyethylene Terephthalate (PET) Sheet, A–523–813	3/3/20–8/31/21
OCTAL SAOC—FZC	
Taiwan: Forged Steel Fittings, A–583–863	9/1/20–8/31/21
Both-Well Steel Fittings, Co., Ltd.	
Taiwan: Narrow Woven Ribbons With Woven Selvedge, A–583–844	9/1/20–8/31/21
A–MADEUS TEXTILE LTD.	
A–MEN Ribbons Co., Ltd.	
Chang Store Co. Ltd a.k.a. Hsien Chan Enterprise Co., Ltd	
Cheng Mei Label Mfg. Corp.	
Christmas Castle International Ltd.	
Dear Year Brothers Mfg. Co., Ltd	
Dearcobber International Co Ltd	
Ethel Enterprise Co., Ltd.	
Everwin Textile Corp.	
Fist Labeling Corp.	
Friend Chiu Co., Ltd.	
Glory Young Enterprise Co., Ltd.	
Golden State Industrial Co. Ltd.	
Great Texture Int'l Co., Ltd.	
Gyrostate Corp.	
Hao Shyang Ind. Co. Ltd.	
Hen Hao Trading Co. Ltd aka Taiwan Tulip Ribbons and Braids Co. Ltd.	
J.S. (Just Splendid) Co., Ltd.	
JCben Enterprises Co. Ltd.	
Junmay Label Mfg Corp.	
King Young Enterprise Co., Ltd.	
King Young Enterprises Co., Ltd.	
Lace Fashions Industrial Co. Ltd.	
Linset Enterprises Co., Ltd.	
Lung Che Ribbons Enterprises Co. Ltd.	
Maple Ribbon Co. Ltd. a.k.a. Pansy Weaving Co/Ltd	
Maxtend Industry Corporation	
May Favor Enterprise Co., Ltd	
N.K. Galleria Inc.	
Nien Chow Industrial Co.	
Novelty Handicrafts Co., Ltd.	
Ren Her Industry Co. Ltd.	
Ribbon City Company	
Roung Shu Industry Corporation a.k.a. Cheng Hsing Ribbon Factory	
Shienq Huong Enterprises Co. Ltd.	
Trio Co., Ltd	
Tse Tien Shin Enterprise Co Ltd	
Tsong Jiaw Enterprise Co., Ltd.	
Wing Hung (Tw) Co Ltd	
Yih Jenq Textile Co. Ltd.	
Yu Shin Development Co. Ltd.	
The People's Republic of China: Certain Magnesia Carbon Bricks, A–570–954	9/1/20–8/31/21
Autong Industry Co., Ltd.	
Dandong Xinxing Carbon Co., Ltd.	
Fedmet Resources Corporation	
Fengchi Imp. and Exp. Co., Ltd.	
Fengchi Imp. and Exp. Co., Ltd. of Haicheng City	
Fengchi Mining Co., Ltd. of Haicheng City	
Fengchi Refractories Co., of Haicheng City	
FRC Global Inc.	
Haicheng Donghe Taidi Refractory Co., Ltd.	
Henan Xintuo Refractory Co., Ltd.	
Liaoning Fucheng Refractories	
Liaoning Zhongmei High Temperature Material Co., Ltd.	
Liaoning Zhongmei Holding Co., Ltd.	
PRCO America Inc.	
Puyang Refractories Co., Ltd.	
Puyang Refractories Group Co., Ltd.	
Qingdao Wonjin Special Refractory Material Co., Ltd.	
RHI Refractories Liaoning Co., Ltd.	
Shenglong Refractories Co., Ltd.	
SL Refractories LLC	
Tangshan Strong Refractories Co., Ltd.	
The Economic Trading Group Of Haicheng Houying Corp. Ltd.	

	Period to be reviewed
Wonjin Refractory Co., Ltd.	
Yingkou Heping Samwha Minerals, Co., Ltd.	
Yingkou Heping Sanhua Materials Co., Ltd.	
Yingkou Hongyu Wonjin Refractory Material Co., Ltd.	
Yingkou Mei'ao Mining Product Co., Ltd.	
Zibo Fubang Wonjin Refractory Technology Co., Ltd.	
Zibo Hengsen Refractory Co., Ltd.	
Zibo Hitech Material Co., Ltd.	
The People's Republic of China: Collated Steel Staples, A–570–112	1/8/20–6/30/21
Unicorn Fasteners Manufacturing Co., Ltd.[7]	
The People's Republic of China: Narrow Woven Ribbons With Woven Selvedge, A–570–952	9/1/20–8/31/21
Amadeus Textile Ltd.	
Amsun Industrial Co., Ltd.	
Beauty Horn Investment Limited	
Bestpak Gifts and Crafts Co., Ltd.	
Billion Trend International Ltd.	
Changle Huanyu Ribbon Weaving Co., Ltd.	
Changle Ruixiang Webbing Co., Ltd.	
Changtai Rongshu Textile Co., Ltd.	
Cheng Xeng Label Mfg. Co.	
Complacent Industrial Co. Ltd. (HK)	
Creative Design Ltd.	
Dong Guan WSJ Weaving Factory Limited	
Dongguan Qaotou Sheng Feng Decoration Factory	
Dongguan Yi Sheng Decoration Co., Ltd.	
Dragon Max Weaving & Accessories Company	
East Sun Gift & Crafts Factory	
Fasheen Accessories Co. Ltd.	
Fly Dragon (Guang zhou) Imports & Exports trading co., Ltd	
Fuhua Industrial Co., Ltd	
Fujian Rongshu Industry Co., Ltd.	
Fujian Shi Lian Da Garment Accessories Co., Ltd.	
Fujian Xin Sheng Da Weaving Ribbons Co., Ltd.	
Fujian Xinshengda Weaving Ribbons Co., Ltd.	
Fung Ming Ribbon Ind Ltd	
Goodyear Webbing Products Co., Ltd	
Goodyear Webbing Products Co., Ltd.	
Gordon Ribbons & Trimmings Co., Ltd.	
Guangzhou Complacent Weaving Co Ltd	
Guangzhou Leiyu Trade Co., Ltd.	
Guangzhou Liman Ribbon Factory	
Guangzhou Mafolen Ribbons & Bows Ltd	
Guangzhou String Textile Accessories Co., Ltd.	
Hubscher Ribbon Corp., Ltd.	
Huian Huida Webbing Co., Ltd.	
Huzhou Linghu Tianyi Tape Co., Ltd.	
Huzhou Unifull Label Fabric Co., Ltd.	
Jian Chang Ind. Co., Ltd.	
Jiangyin Lilai Tape Co., Ltd.	
Jufeng Ribbon Co.Ltd.	
Kaiping Qifan Weaving Co., Ltd.	
King's Pipe Cleaner's Ind. Inc aka King's Crafts (China) Ltd	
(aka King's Pipe Cleaner's, Ind. Inc)	
Kinstarlace & Embroidery Co.	
Kunshan Dah Mei Weaving Co. Ltd.	
Lace Fashions Industrial Co. Ltd.	
Linghu Jiacheng Silk Ribbon Co., Ltd.	
Ningbo Bofa Co., Ltd	
Ningbo Flowering Crafts Co., Ltd.	
Ningbo Hongshine Decorative Packing Industrial Co. Ltd. aka Ningbo Hongrun	
Craft and Ornament Factory	
Ningbo Jinfeng Thread & Ribbon Co. Ltd.	
Ningbo MH Industry Co., Ltd.	
Ningbo R&D Ind Company	
Ningbo Sunshine Import & Export Co. Ltd	
Ningbo V.K. Industry and Trading Co., Ltd.	
Ningbo Wanhe Industry Co., Ltd.	
Ningbo XWZ Ribbon Manufactory	
Ningbo Yinzhou Hengcheng Ribbon Factory	
Ningbo Yinzhou Jinfeng Knitting Factory	
PROTEX Co., ltd	
Qingdao Cuifengyuan Industrial and Trading Co., Ltd.	
Qingdao Haili Lace & Ribbon Co., Ltd.	
Qingdao Hileaders Co.,Ltd.	

	Period to be reviewed
RizeStar Weaving Ribbon Factory	
Shandong Hileaders Industrial Co., Ltd.	
Shanghai Dae Textile International Co., Ltd.	
Shanghai E & T Jawa Import & Export Co. Ltd.	
ShaoXing Haiyue Gifts Co. Ltd.	
Shenq Sin Company Ltd.	
Shenzhen Bostrip Crafts Co. Ltd.	
Shenzhen Candour Belt & Tape Co., Ltd.	
Shenzhen Jinpin Gifts & Crafts Factory	
Shenzhen Lucky Star Craft Co., Ltd.	
Shenzhen Weiyi Crafts Technology Co.,Ltd.	
Shenzhen Yibao Gifts Co. Ltd.	
Shishi Lifa Computer Woven Label Co., Ltd.	
Shuanglin Label	
Sinopak Gifts & Crafts Co., Ltd	
Stribbons (Guangzhou) Ltd. aka MNC Stribbons	
Stribbons (Nanyang) MNC Ltd.	
String Textile Accessories Co., Ltd.	
String Textile Accessories Co., Ltd.	
Success Charter Enterprise Limited	
Sun Rich (Asia) Limited	
Sungai Garment Accessories Co., Ltd.	
Tianjin Sun Ribbon Company Ltd aka Tian Jin Sun Ribbon Company Ltd.	
Weifang Aofulon Weaving Company Ltd	
Weifang Chenrui Textile Co., Ltd.	
Weifang Dongfang Ribbon Weaving Co. Ltd.	
Weifang Jiacheng Webbing Co., Ltd.	
Weifang Jinqi Textile Co., Ltd.	
Weifang Yuyuan Textile Co. Ltd.	
Wenzhou GED Industrial Co. Ltd.	
Wiefang Shicheng Ribbon Factory	
Wing Tat Haberdashery Co. Ltd aka Wing Hiang Belt Weaving Ltd.	
Xiamen Bailuu Thread Manufacture Co., Ltd.	
Xiamen Bethel Ribbon & Trims Co., Ltd.	
Xiamen Boca Ribbons & Crafts Co., Ltd.	
Xiamen Egret Thread Manufacturing Co., Ltd.	
Xiamen Especial Industrial Co., Ltd.	
Xiamen Lianglian Ribbons & Bows Co., Ltd	
Xiamen Linji Ribbons & Bows Co., Ltd.	
Xiamen Lude Ribbons And Bows Co., Ltd.	
Xiamen Midi Ribbons & Crafts Co., Ltd.	
Xiamen Rainbow Gifts & Packs Co., Ltd.	
Xiamen Sanling Ribbon Packing Co., Ltd.	
Xiamen ShangPeng Weaving Ribbon Factory	
Xiamen Sling Ribbon & Bows Co., Ltd.	
Xiamen Yi He Textile Co., Ltd.	
Yangzhou Bestpak Gifts and Crafts Co., Ltd.	
Yi Jia Trimmings Accessories & Supplies	
Yiwu Baijin Belt Co., Ltd	
Yiwu City Pingzhan Weaving Ribbon Factory	
Yiwu Dong Ding Ribbons Co., Ltd.	
Yiwu Ruitai Webbing Factory	
Yiwu Yunli Tape Co., Ltd.	
Yuanhong Garment Accessory Co., Ltd.	
Yuyao Warp & Weft Tape Weaving Co., Ltd.	
Zenith Garment Accessories Co., Ltd.	
Zhejiang Chengxin Weaving Co., Ltd	
Zhejiang Sanding Weaving Co. Ltd.	
Zibo All Webbing Co., Ltd.	
The People's Republic of China: Steel Racks, A–570–088	9/1/20–8/31/21
Ateel Display Industries (Xiamen) Co., Ltd.	
CTC Universal (Zhangzhou) Industrial Co., Ltd.	
David Metal Craft Manufactory Ltd.	
Fujian Ever Glory Fixtures Co., Ltd.	
Guangdong Wireking Housewares and Hardware Co., Ltd.	
Hebei Minmetals Co., Ltd.	
Hebei Wuxin Garden Products Co., Ltd.	
Huanghua Xinxing Furniture Co., Ltd.	
i-Lift Equipment Ltd.	
Johnson (Suzhou) Metal Products Co., Ltd.	
Master Trust (Xiamen) Import and Export Co., Ltd.	
Nanjing Dongsheng Shelf Manufacturing Co., Ltd.	
Nanjing Ironstone Storage Equipment Co., Ltd.	
Nanjing Kingmore Logistics Equipment Manufacturing Co., Ltd.	

	Period to be reviewed
Ningbo Xinguang Rack Co., Ltd.	
Redman Corporation	
Redman Import & Export Limited	
Suzhou (China) Sunshine Hardware & Equipment Imp. & Exp. Co. Ltd.	
Tianjin Master Logistics Equipment Co., Ltd.	
Xiamen Baihuide Manufacturing Co., Ltd.	
Xiamen Ever Glory Fixtures Co., Ltd.	
Xiamen Golden Trust Industry & Trade Co., Ltd.	
Xiamen Kingfull Imp and Exp Co., Ltd. (d.b.a) Xiamen Kingfull Displays Co., Ltd.	
Xiamen LianHong Industry and Trade Co., Ltd.	
Xiamen Luckyroc Industry Co., Ltd.	
Xiamen Luckyroc Storage Equipment Manufacture Co., Ltd.	
Xiamen Meitoushan Metal Products Co., Ltd.	
Xiamen Power Metal Display Co., Ltd.	
Xiamen XinHuiYuan Industrial & Trade Co., Ltd.	
Xiamen Yiree Display Fixtures Co., Ltd.	
Zhangjiagang Better Display Co., Ltd.	
CVD Proceedings	
Republic of Korea: Cold-Rolled Steel Flat Products, C–580–882	1/1/20–12/31/20
AJU Steel Co., Ltd.	
Amerisource Korea	
Amerisource International	
BC Trade	
Busung Steel Co., Ltd.	
Cenit Co., Ltd.	
Daewoo Logistics Corp.	
Dai Yang Metal Co., Ltd.	
DK GNS Co., Ltd.	
Dongbu Incheon Steel Co., Ltd.	
Dongbu Steel Co., Ltd.	
Dong Jin Machinery	
Dongkuk Industries Co., Ltd.	
Dongkuk Steel Mill Co., Ltd.	
Eunsan Shipping and Air Cargo Co., Ltd.	
Euro Line Global Co., Ltd.	
Golden State Corp.	
GS Global Corp.	
Hanawell Co., Ltd.	
Hankum Co., Ltd.	
Hyosung TNC Corp.	
Hyuk San Profile Co., Ltd.	
Hyundai Group	
Hyundai Steel Co., Ltd.	
Iljin NTS Co., Ltd.	
Iljin Steel Corp.	
Jeen Pung Industrial Co., Ltd.	
JT Solution	
KG Dongbu Steel Co., Ltd.	
Kolon Global Corporation	
Nauri Logistics Co., Ltd.	
Okaya (Korea) Co., Ltd.	
PL Special Steel Co., Ltd.	
POSCO	
POSCO C&C Co., Ltd.	
POSCO Daewoo Corp.	
POSCO International Corporation.	
Samsung C&T Corp.	
Samsung STS Co., Ltd.	
SeAH Steel Corp.	
SM Automotive Ltd.	
SK Networks Co., Ltd.	
Taihan Electric Wire Co., Ltd.	
TGS Pipe Co., Ltd.	
TI Automotive Ltd.	
Xeno Energy	
Young Steel Co., Ltd.	
Socialist Republic of Vietnam: Utility Scale Wind Towers, C–552–826	12/13/19–12/31/20
CS Wind Vietnam Co., Ltd.[8]	
The People's Republic of China: Narrow Woven Ribbons With Woven Selvedge, C–570–953	1/1/20–12/31/20
Amadeus Textile Ltd.	
Amsun Industrial Co., Ltd.	
Beauty Horn Investment Limited	
Bestpak Gifts and Crafts Co., Ltd.	

	Period to be reviewed
Billion Trend International Ltd. Changle Huanyu Ribbon Weaving Co., Ltd. Changle Ruixiang Webbing Co., Ltd. Changtai Rongshu Textile Co., Ltd. Cheng Xeng Label Mfg. Co. Complacent Industrial Co. Ltd. (HK) Creative Design Ltd. Dongguan Qaotou Sheng Feng Decoration Factory Dongguan Yi Sheng Decoration Co., Ltd. Dragon Max Weaving & Accessories Company East Sun Gift & Crafts Factory Fasheen Accessories Co. Ltd. Fly Dragon (Guang zhou) Imports & Exports trading co., Ltd Fuhua Industrial Co., Ltd Fujian Rongshu Industry Co., Ltd. Fujian Shi Lian Da Garment Accessories Co., Ltd. Fujian Xin Shen Da Weaving Ribbons Co., Ltd. Fujian Xinshengda Weaving Ribbons Co., Ltd. Fung Ming Ribbon Ind Ltd Goodyear Webbing Products Co., Ltd. Gordon Ribbons & Trimmings Co., Ltd. Guangzhou Complacent Weaving Co Ltd Guangzhou Leiyu Trade Co., Ltd. Guangzhou Liman Ribbon Factory Guangzhou Mafolen Ribbons & Bows Ltd Guangzhou String Textile Accessories Co., Ltd. Huian Huida Webbing Co., Ltd. Huzhou Linghu Tianyi Tape Co., Ltd. Huzhou Unifull Label Fabric Co., Ltd. Jian Chang Ind. Co., Ltd. Jiangyin Lilai Tape Co., Ltd. Jufeng Ribbon Co. Ltd. Kaiping Qifan Weaving Co., Ltd. King's Pipe Cleaner's Ind. Inc aka King's Crafts (China) Ltd (aka King's Pipe Cleaner's, Ind. Inc) Kinstarlace & Embroidery Co. Kunshan Dah Mei Weaving Co. Ltd. Lace Fashions Industrial Co. Ltd. Linghu Jiacheng Silk Ribbon Co., Ltd. Ningbo Bofa Co., Ltd Ningbo Flowering Crafts Co., Ltd. Ningbo Hongshine Decorative Packing Industrial Co. Ltd. aka Ningbo Hongrun Craft and Ornament Factory Ningbo Jinfeng Thread & Ribbon Co. Ltd. Ningbo MH Industry Co., Ltd. Ningbo R&D Ind Company Ningbo Sunshine Import & Export Co. Ltd Ningbo V.K. Industry and Trading Co., Ltd. Ningbo Wanhe Industry Co., Ltd. Ningbo XWZ Ribbon Manufactory Ningbo Yinzhou Hengcheng Ribbon Factory Ningbo Yinzhou Jinfeng Knitting Factory PROTEX Co., ltd Qingdao Cuifengyuan Industrial and Trading Co., Ltd. Qingdao Haili Lace & Ribbon Co., Ltd. Qingdao Hileaders Co., Ltd. RizeStar Weaving Ribbon Factory Shandong Hileaders Industrial Co., Ltd. Shanghai Dae Textile International Co., Ltd. Shanghai E & T Jawa Import & Export Co. Ltd. ShaoXing Haiyue Gifts Co. Ltd. Shenq Sin Company Ltd. Shenzhen Bostrip Crafts Co. Ltd. Shenzhen Candour Belt & Tape Co., Ltd. Shenzhen Jinpin Gifts & Crafts Factory Shenzhen Lucky Star Craft Co., Ltd. Shenzhen Weiyi Crafts Technology Co., Ltd. Shenzhen Yibao Gifts Co. Ltd. Shishi Lifa Computer Woven Label Co., Ltd. Shuanglin Label Sinopak Gifts & Crafts Co., Ltd Stribbons (Guangzhou) Ltd. Aka MNC Ribbons Stribbons (Nanyang) MNC Ltd. String Textile Accessories Co., Ltd. Success Charter Enterprise Limited Sun Rich (Asia) Limited	

	Period to be reviewed
Sungai Garment Accessories Co., Ltd.	
Tianjin Sun Ribbon Company Ltd aka Tian Jin Sun Ribbon Company Ltd.	
Weifang Aofulon Weaving Company Ltd.	
Weifang Chenrui Textile Co., Ltd.	
Weifang Dongfang Ribbon Weaving Co. Ltd.	
Weifang Jiacheng Webbing Co., Ltd.	
Weifang Jinqi Textile Co., Ltd.	
Weifang Yuyuan Textile Co. Ltd.	
Wenzhou GED Industrial Co. Ltd.	
Wiefang Shicheng Ribbon Factory	
Wing Tat Haberdashery Co. Ltd aka Wing Hiang Belt Weaving Ltd.	
Xiamen Bailuu Thread Manufacture Co., Ltd.	
Xiamen Bethel Ribbon & Trims Co., Ltd.	
Xiamen Boca Ribbons & Crafts Co., Ltd.	
Xiamen Egret Thread Manufacturing Co., Ltd.	
Xiamen Especial Industrial Co., Ltd.	
Xiamen Lianglian Ribbons & Bows Co., Ltd	
Xiamen Linji Ribbons & Bows Co., Ltd.	
Xiamen Lude Ribbons And Bows Co., Ltd.	
Xiamen Midi Ribbons & Crafts Co., Ltd.	
Xiamen Rainbow Gifts & Packs Co., Ltd.	
Xiamen Sanling Ribbon Packing Co., Ltd.	
Xiamen ShangPeng Weaving Ribbon Factory	
Xiamen Sling Ribbon & Bows Co., Ltd.	
Xiamen Yi He Textile Co., Ltd. (d/b/a Roungshu Ribbon)	
Yama Ribbons and Bows Co., Ltd.	
Yangzhou Bestpak Gifts and Crafts Co., Ltd.	
Yi Jia Trimmings Accessories & Supplies/Dong Guan WSJ Weaving Factory Limited	
Yiwu Baijin Belt Co., Ltd	
Yiwu City Pingzhan Weaving Ribbon Factory	
Yiwu Dong Ding Ribbons Co., Ltd.	
Yiwu Ruitai Webbing Factory	
Yiwu Yunli Tape Co., Ltd.	
Yuanhong Garment Accessory Co., Ltd.	
Yuyao Warp & Weft Tape Weaving Co., Ltd.	
Zenith Garment Accessories Co., Ltd.	
Zhejiang Chengxin Weaving Co., Ltd	
Zhejiang Sanding Weaving Co. Ltd.	
Zibo All Webbing Co., Ltd.	
The People's Republic of China: Steel Racks, C–570–089	1/1/20–12/31/20
Ateel Display Industries (Xiamen) Co., Ltd	
CTC Universal (Zhangzhou) Industrial Co., Ltd	
David Metal Craft Manufactory Ltd	
Fujian Ever Glory Fixtures Co., Ltd	
Guangdong Wireking Housewares and Hardware Co., Ltd	
Hebei Minmetals Co., Ltd	
Hebei Wuxin Garden Products Co., Ltd	
Huanghua Xinxing Furniture Co., Ltd	
i-Lift Equipment Ltd	
Johnson (Suzhou) Metal Products Co., Ltd	
Master Trust (Xiamen) Import and Export Co., Ltd	
Nanjing Dongsheng Shelf Manufacturing Co., Ltd	
Nanjing Dongsheng Shelf Manufacturing Co., Ltd.	
Nanjing Ironstone Storage Equipment Co., Ltd	
Nanjing Ironstone Storage Equipment Co., Ltd.	
Nanjing Kingmore Logistics Equipment Manufacturing Co., Ltd	
Ningbo Xinguang Rack Co., Ltd	
Redman Corporation	
Redman Import & Export Limited	
Suzhou (China) Sunshine Hardware & Equipment Imp. & Exp. Co. Ltd	
Tianjin Master Logistics Equipment Co., Ltd	
Xiamen Baihuide Manufacturing Co., Ltd	
Xiamen Ever Glory Fixtures Co., Ltd	
Xiamen Golden Trust Industry & Trade Co., Ltd	
Xiamen Kingfull Imp and Exp Co., Ltd. (d.b.a) Xiamen Kingfull Displays Co., Ltd	
Xiamen LianHong Industry and Trade Co., Ltd	
Xiamen Luckyroc Industry Co., Ltd	
Xiamen Luckyroc Storage Equipment Manufacture Co., Ltd	
Xiamen Meitoushan Metal Products Co., Ltd	
Xiamen Power Metal Display Co., Ltd	
Xiamen XinHuiYuan Industrial & Trade Co., Ltd	
Xiamen Yiree Display Fixtures Co., Ltd	
Zhangjiagang Better Display Co., Ltd	

	Period to be reviewed
Suspension Agreements	
Fresh Tomatoes, A–201–820	9/1/20–8/31/21

Duty Absorption Reviews

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an AD order under 19 CFR 351.211 or a determination under 19 CFR 351.218(f)(4) to continue an order or suspended investigation (after sunset review), Commerce, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine whether AD duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

Gap Period Liquidation

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant ''gap'' period of the order (*i.e.,* the period following the expiry of provisional measures and before definitive measures were put into place), if such a gap period is applicable to the POR.

Administrative Protective Orders and Letters of Appearance

Interested parties must submit applications for disclosure under administrative protective orders in accordance with the procedures outlined in Commerce's regulations at 19 CFR 351.305. Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that they meet the requirements of these procedures (*e.g.,* the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

Factual Information Requirements

Commerce's regulations identify five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). These regulations require any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. The regulations, at 19 CFR 351.301, also provide specific time limits for such factual submissions based on the type of factual information being submitted. Please review the *Final Rule,*[9] available at *https://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt,* prior to submitting factual information in this segment. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[10]

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information using the formats provided at the end of the *Final Rule.*[11] Commerce intends to reject factual submissions in any proceeding segments if the submitting party does not comply with applicable certification requirements.

Extension of Time Limits Regulation

Parties may request an extension of time limits before a time limit established under Part 351 expires, or as otherwise specified by Commerce.[12] In general, an extension request will be considered untimely if it is filed after the time limit established under Part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Examples include, but are not limited to: (1) Case and rebuttal briefs, filed pursuant to 19 CFR 351.309; (2) factual information to value factors under 19 CFR 351.408(c), or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2), filed pursuant to 19 CFR 351.301(c)(3) and rebuttal, clarification and correction filed pursuant to 19 CFR 351.301(c)(3)(iv); (3) comments concerning the selection of a surrogate country and surrogate values and rebuttal; (4) comments concerning CBP data; and (5) Q&V questionnaires. Under certain circumstances, Commerce may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, Commerce will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This policy also requires that an extension request must be made in a separate, stand-alone submission, and clarifies the circumstances under which Commerce will grant untimely-filed requests for the extension of time limits. Please review the *Final Rule,* available at *https://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these segments.

These initiations and this notice are in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: November 2, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2021–24228 Filed 11–4–21; 8:45 am]

BILLING CODE 3510–DS–P

[9] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* the frequently asked questions regarding the *Final Rule,* available at *https://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

[10] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 41363 (July 10, 2020).

[11] *See* section 782(b) of the Act; *see also Final Rule;* and the frequently asked questions regarding the *Final Rule,* available at *https://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

[12] *See* 19 CFR 351.302.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–853]

Certain Crystalline Silicon Photovoltaic Products From Taiwan: Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2020–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In response to requests from interested parties, the Department of Commerce (Commerce) is rescinding the administrative review, in part, of the antidumping duty order on certain crystalline silicon photovoltaic products (solar products) from Taiwan during the period of review (POR), February 1, 2020, to January 31, 2021. Specifically, Commerce is rescinding the review with respect to eleven companies under review, including the mandatory respondents, Inventec Solar Energy Corporation (ISEC) and Sino-American Silicon Products Inc. (SAS), because all requests to review these companies have been timely withdrawn. Moreover, Commerce preliminarily determines that sixteen of the companies under review made no shipments of solar products from Taiwan during the POR. Finally, with respect to the companies that did not submit no-shipment certifications and were not selected as mandatory respondents, we have determined to preliminarily apply a rate of 7.89 percent, *i.e.,* the non-selected rate from the prior administrative review under this antidumping duty order. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 5, 2021.

FOR FURTHER INFORMATION CONTACT: Thomas Martin or Zachary Shaykin, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3936 or (202) 482–2638, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2021, in accordance with 19 CFR 351.221(c)(1)(i), we initiated this administrative review of the antidumping duty order on solar products from Taiwan [1] covering thirty-one producers and/or exporters of the subject merchandise.[2] On June 10, 2021, Commerce selected ISEC and SAS as the mandatory respondents.[3]

On June 3, 2021, SunPower Manufacturing Oregon LLC (SPMOR, a domestic producer and domestic interested party) withdrew its request for administrative review of all twenty-nine companies it originally requested,[4] and on June 30, 2021, Auxin Solar, Inc. (Auxin, a domestic producer, domestic importer, and domestic interested party) withdrew its request for review of eleven of the thirty-one companies it originally requested, including the mandatory respondents.[5] Accordingly, pursuant to 19 CFR 351.213(d)(1), Commerce is rescinding the administrative review, in part, with respect to the companies fully withdrawn by SPMOR and Auxin. The review remains active with respect to the remaining 20 companies.[6]

[1] *See Certain Crystalline Silicon Photovoltaic Products from Taiwan: Antidumping Duty Order,* 80 FR 8596 (February 18, 2015) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 17124, 17131 (April 1, 2021) (*Initiation Notice*).

[3] *See* Memorandum, ''2020–2021 Antidumping Duty Administrative Review of Certain Crystalline Silicon Photovoltaic Products from Taiwan: Respondent Selection,'' dated June 10, 2021.

[4] *See* SPMOR's Letter, ''Certain Crystalline Silicon Photovoltaic Products from Taiwan—Withdrawal of Request for Administrative Review,'' dated June 3, 2021 (SPMOR's Withdrawal Request).

[5] *See* Auxin's Letter, ''Certain Crystalline Silicon Photovoltaic Products from Taiwan: Withdrawal of Request for Administrative Review of Antidumping Order,'' dated June 30, 2021 (Auxin's Withdrawal Request). Auxin withdrew its request for administrative review with respect to the following companies: (1) EEPV Corporation; (2) E–TON Solar Tech. Co., Ltd.; (3) Inventec Energy Corporation; (4) Inventec Solar Energy Corporation; (5) Ming Hwei Energy Co., Ltd.; (6) Motech Industries, Inc.; (7) SAS; (8) Sunengine Corporation Ltd.; (9) TSEC Corporation; (10) United Renewable Energy Co., Ltd.; and (11) Win Win Precision Technology Co., Ltd.

[6] The remaining companies in this administrative review are: (1) AU Optronics Corporation; (2) Baoding Jiasheng Photovoltaic Technology Co. Ltd. (Baoding Jiasheng); (3) Baoding Tianwei Yingli New Energy Resources Co., Ltd.; (4) Beijing Tianneng Yingli New Energy Resources CO. Ltd.; (5) Boviet Solar Technology Co., Ltd. (Boviet); (6) Canadian Solar Inc.; (7) Canadian Solar International, Ltd.; (8) Canadian Solar Manufacturing (Chang shu), Inc.; (9) Canadian Solar Manufacturing (Luoyang), Inc.; (10) Canadian Solar Solution Inc.; (11) Hainan Yingli New Energy Resources Co., Ltd.; (12) Hengshui Yingli New Energy Resources Co., Ltd.; (13) Kyocera Mexicana S.A. de C.V. (Kyocera); (14) Lixian Yingli New Energy Resources Co., Ltd.; (15) Shenzhen Yingli New Energy Resources Co., Ltd.; (16) Sunrise Energy Co. Ltd. (Sunrise); (17) Tianjin Yingli New Energy Resources Co., Ltd.; (18) Vina Solar; (19) Yingli Energy (China) Co., Ltd.; and (20) Yingli Green Energy International Trading Company Limited.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of Tariff Act of 1930, as amended (the Act).

Scope of the Order

The products covered by the *Order* are solar products from Taiwan.[7] Imports of subject merchandise are classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 8501.61.0010, 8507.20.80, 8541.40.6015, 8541.40.6025, and 8501.31.8010. These HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope of the *Order* is dispositive.[8]

Rescission of Administrative Review in Part

Section 351.213(d)(1) of Commerce's regulations provides that Commerce will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request for review within 90 days of the date of publication of the notice of initiation of the requested review. Commerce published the *Initiation Notice* on April 1, 2021.[9] On June 3, 2021, SPMOR withdrew its request for review for all twenty-nine companies it had requested.[10] On June 30, 2021, Auxin withdrew its request for review of eleven of the thirty-one companies it had originally requested: (1) EEPV CORP.; (2) E–TON Solar Tech. Co., Ltd.; (3) Inventec Energy Corporation; (4) ISEC; (5) Ming Hwei Energy Co., Ltd.; (6) Motech Industries, Inc.; (7) SAS; (8) Sunengine Corporation Ltd.; (9) TSEC Corporation; (10) United Renewable Energy Co., Ltd.; and (11) Win Win Precision Technology Co., Ltd.[11] Because the review requests for these eleven companies were timely withdrawn, and because no other party requested a review of any of them, we are rescinding the reviews with respect to the eleven companies stated above. The review will continue with respect to all other entities listed in the *Initiation Notice.*

Preliminary Determination of No Shipments

Sixteen producers and/or exporters under review properly filed a certification reporting that they made no shipments of subject merchandise during the POR: (1) AU Optronics

[7] *See Order.*

[8] *Id.*

[9] *See Initiation Notice.*

[10] *See* SPMOR's Withdrawal Request.

[11] *See* Auxin's Withdrawal Request.

Corporation (AU);[12] (2) Canadian Solar Inc., (3) Canadian Solar International Limited, (4) Canadian Solar Manufacturing (Changshu), Inc., (5) Canadian Solar Manufacturing (Luoyang), Inc., (6) Canadian Solar Solutions Inc. (the Canadian companies);[13] (7) Vina Solar Technology Co., Ltd. (Vina Solar);[14] (8) Baoding Tianwei Yingli New Energy Resources Co., Ltd.; (9) Beijing Tianneng Yingli New Energy Resources Co., Ltd.; (10) Hainan Yingli New Energy Resources Co., Ltd.; (11) Hengshui Yingli New Energy Resources Co., Ltd.; (12) Lixian Yingli New Energy Resources Co., Ltd.; (13) Shenzhen Yingli New Energy Resources Co., Ltd.; (14) Tianjin Yingli New Energy Resources Co., Ltd.; (15) Yingli Energy (China) Co., Ltd.; and (16) Yingli Green Energy International Trading Company Limited (Yingli).[15] On May 17, 2021, Vina Solar, the only potential respondent left in this administrative review with reviewable entries of subject merchandise during the POR, commented on Commerce's U.S. Customs and Border Protection (CBP) data release[16] that it made no shipments of subject merchandise to the United States during the POR, and that Commerce should revise the CBP data.[17] No other parties commented on the CBP data release. We contacted CBP to corroborate Vina Solar's statements during the POR. We requested entry summaries from CBP to determine that Vina Solar had no entries of subject merchandise during the POR. We reviewed the entry summaries we received from CBP. Based on our analysis of these entry summaries, we did not find any information to contradict Vina Solar's claims of no shipments during the POR.[18] Therefore, we preliminarily determine that none of the above sixteen companies (*i.e.,* including Vina Solar) had shipments of subject merchandise during the POR.

Consistent with Commerce's practice,[19] Commerce finds that it is not appropriate to rescind the review with respect to these sixteen companies, but rather to complete the review and issue appropriate instructions to CBP based on the final results of this review.

Rate for Non-Examined Companies

The statute and Commerce's regulations do not address the establishment of a rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a less-than-fair-value investigation, for guidance when calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted-average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely {on the basis of facts available}.''

In the instant review, the CBP data query[20] did not show any entries of subject merchandise exported by Baoding Jiasheng, Boviet, Kyocera, or Sunrise[21] during the POR, the remaining non-selected respondents that did not submit a certification of no shipments. Thus, there is no basis for selecting any of the above companies as mandatory respondents.[22] Accordingly, because there are no companies in the instant review for which we are calculating a rate that can be applied to the above companies, we have determined to preliminarily apply a rate of 7.89 percent to Baoding Jiasheng, Boviet, Kyocera, and Sunrise as non-selected respondents, which is the weighted-average dumping margin determined and assigned to the non-selected respondents in the previous (fifth) administrative review of the *Order.*[23]

Public Comment

Interested parties may submit case briefs no later than 30 days after the date of publication of this notice.[24] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the time limit for filing case briefs.[25] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[26] Case and rebuttal briefs must be filed electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) and must also be served on interested parties.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed document must be received successfully in its entirety in ACCESS by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.[27] Hearing requests should contain: (1) The interested party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined.[28] Commerce intends to issue the final results of this administrative review, including the results of its analysis raised in any written briefs, no later than 120 days after the publication of these preliminary results in the **Federal Register**, unless otherwise extended.[29]

Assessment Rates

Upon issuance of the final results, Commerce will determine, and CBP

[12] *See* AU's Letter, ''Certain Crystalline Silicon Photovoltaic Products from Taiwan—Notice of No Sales or Exports,'' dated April 20, 2021.

[13] *See* Canadian Companies' Letter, ''Crystalline Silicon Photovoltaic Products from Taiwan, Case No. A–583–853: No Shipment Letter,'' dated April 27, 2021.

[14] *See* Vina Solar's Letter, ''Certain Crystalline Silicon Photovoltaic Products from Taiwan—Notice of No Sales or Exports,'' dated April 30, 2021.

[15] *See* Yingli's Letter, ''Certain Crystalline Silicon Photovoltaic Products from Taiwan: Yingli's No Shipment Certification,'' dated April 30, 2021.

[16] *See* Memorandum, ''Certain Crystalline Silicon Photovoltaic Products from Taiwan: Release of Customs and Border Protection Data,'' dated May 10, 2021 (CBP Data Release).

[17] *See* Vina Solar's Letter, ''Certain Crystalline Silicon Photovoltaic Products from Taiwan: Comment on CBP Data,'' dated May 17, 2021.

[18] Commerce issued a no-shipment inquiry to CBP on June 6, 2021. *See* Memorandum, ''Notification of Receipt of U.S. Entry Documents,'' dated July 2, 2021.

[19] *See, e.g., Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Turkey: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2017–2018,* 84 FR 34863 (July 19, 2019), and accompanying Preliminary Decision Memorandum at 4.

[20] *See* CBP Data Release.

[21] These three companies are the remaining non-selected respondents in this review that did not submit letters of no shipment.

[22] *See* CBP Data Release at Attachment.

[23] *See Certain Crystalline Silicon Photovoltaic Products from Taiwan: Final Results of Antidumping Duty Administrative Review; Partial Rescission of Antidumping Duty Administrative Review; Final Determination of No Shipments; 2019–2020,* 86 FR 49509, 49510–11 (September 3, 2021), and accompanying Issues and Decision Memorandum.

[24] *See* 19 CFR 351.309(c)(1)(ii).

[25] *See* 19 CFR 351.309(d)(1).

[26] *See* 19 CFR 351.309(c)(2) and (d)(2); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[27] *See* 19 CFR 351.310(c).

[28] *Id.*

[29] *See* section 751(a)(3)(A) of the Act; *see also* 19 CFR 351.213(h).

shall assess, antidumping duties on all appropriate entries covered by this review.[30] Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

As discussed above, we are rescinding the review with respect to eleven companies, including the mandatory respondents. For the companies that were not selected for individual examination but did not file no shipment certifications, upon issuance of the final results, we will instruct CBP to assess antidumping duties at an *ad valorem* rate equal to the non-selected rate, which we preliminarily determine to be 7.89 percent, as described above.

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by each respondent which did not know that its merchandise was destined for the United States, and for all the companies for which we reach final findings of no shipments, we will instruct CBP to liquidate entries not reviewed at the all-others rate established in the original less-than-fair value (LTFV) investigation (*i.e.,* 19.50 percent) if there is no rate for the intermediate company(ies) involved in the transaction.

Cash Deposit Requirements

The following cash deposit requirements will be in effect for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the companies receiving the non-selected rate will be the rate established in the final results of this review, (except if the rate is de minimis within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero); (2) For merchandise exported by manufacturers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment; (3) if the exporter is not a firm covered in a prior review, or the original investigation, but the manufacturer is, then the cash deposit rate will be the rate established for the most recently completed segment for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 19.50 percent, the all-others cash deposit rate established in the *Final Determination* of the less than fair value investigation of solar products from Taiwan.[31] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h)(1) and 351.221(b)(4).

Dated: November 1, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–24257 Filed 11–4–21; 8:45 am]

BILLING CODE 3510–DS–P

[30] *See* 19 CFR 351.212(b).

[31] *See Certain Crystalline Silicon Photovoltaic Products from Taiwan: Final Determination of Sales at Less Than Fair Value,* 79 FR 76966 (December 23, 2014).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–928]

Uncovered Innerspring Units From the People's Republic of China: Preliminary Determination of No Shipments; 2020–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Comfort Coil Technology Sdn. Bhd. (Comfort Coil), the only company subject to review, had no shipments of subject merchandise during the period of review (POR), February 1, 2020, through January 31, 2021. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 5, 2021.

FOR FURTHER INFORMATION CONTACT: Christopher Maciuba, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0413.

SUPPLEMENTARY INFORMATION:

Background

On February 2, 2021, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order on uncovered innerspring units (innersprings) from the People's Republic of China (China) for the POR.[1] On April 1, 2021, in response to a timely request from Leggett & Platt, Incorporated (the petitioner),[2] and in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.221(c)(1)(i), we initiated an administrative review of the *Order* with respect to Comfort Coil.[3]

Scope of the Order

The merchandise subject to the *Order* is uncovered innerspring units composed of a series of individual metal springs joined together in sizes corresponding to the sizes of adult mattresses (*e.g.,* twin, twin long, full, full long, queen, California king and king) and units used in smaller constructions, such as crib and youth mattresses. All uncovered innerspring units are included in the scope regardless of width and length. Included within this definition are innersprings typically ranging from 30.5 inches to 76 inches in width and 68 inches to 84 inches in length. Innersprings for crib mattresses typically range from 25 inches to 27 inches in width and 50 inches to 52 inches in length.

Uncovered innerspring units are suitable for use as the innerspring component in the manufacture of innerspring mattresses, including

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 86 FR 7855 (February 2, 2021); *see also Uncovered Innerspring Units from the People's Republic of China: Notice of Antidumping Duty Order,* 74 FR 7661 (February 19, 2009) (*Order*).

[2] *See* Petitioner's Letter, ''Uncovered Innerspring Units from the People's Republic of China: Request for 2020–2021 Antidumping Duty Administrative Review,'' dated March 1, 2021.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 17124 (April 1, 2021).

mattresses that incorporate a foam encasement around the innerspring.

Pocketed and non-pocketed innerspring units are included in this definition. Non-pocketed innersprings are typically joined together with helical wire and border rods. Non-pocketed innersprings are included in this definition regardless of whether they have border rods attached to the perimeter of the innerspring. Pocketed innersprings are individual coils covered by a ''pocket'' or ''sock'' of a nonwoven synthetic material or woven material and then glued together in a linear fashion.

Uncovered innersprings are classified under subheading 9404.29.9010 and have also been classified under subheadings 9404.10.0000, 9404.29.9005, 9404.29.9011, 7326.20.0070, 7326.20.0090, 7320.20.5010, 7320.90.5010, or 7326.20.0071 of the Harmonized Tariff Schedule of the United States (HTSUS).[4] The HTSUS subheadings are provided for convenience and customs purposes only; the written description of the scope of the *Order* is dispositive.

Preliminary Determination of No Shipments

On April 23, 2021, we released the U.S. Customs and Border Protection (CBP) entry data of subject merchandise exported to the United States by Comfort Coil during the POR.[5] This query returned no entries during the POR.[6] Thereafter, we received a timely submission from Comfort Coil certifying that it did not have sales, shipments, or exports of subject merchandise to the United States during the POR.[7] We submitted a no-shipments inquiry to CBP with regard to Comfort Coil, to which CBP responded that it found no shipments of subject merchandise by Comfort Coil during the POR.[8]

Accordingly, and consistent with our practice, we preliminarily determine that Comfort Coil had no shipments and, therefore, no reviewable entries, of subject merchandise during the POR. In addition, we find it is not appropriate to rescind the review with respect to this company, but rather, to complete the review with respect to Comfort Coil and issue appropriate instructions to CBP based on the final results of the review, consistent with our practice in non-market economy (NME) cases.[9]

China-Wide Entity

Commerce's policy regarding conditional review of the China-wide entity applies to this administrative review.[10] Under this policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity, and we did not self-initiate a review, the China-wide entity rate (*i.e.,* 234.51 percent) is not subject to change as a result of this review.[11] Aside from Comfort Coil, we did not receive a review request for any other company.

Public Comment

Interested parties are invited to comment on the preliminary results and may submit case briefs and/or written comments, filed electronically via Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS), within 30 days after the date of publication of these preliminary results of review.[12] ACCESS is available to registered users at *https://access.trade.gov.* Rebuttal briefs, limited to issues raised in the case briefs, must be filed within seven days after the time limit for filing case briefs.[13] Parties who submit case or rebuttal briefs in this proceeding are requested to submit with each argument a statement of the issue, a brief summary of the argument, and a table of authorities.[14] Note that Commerce has temporarily modified certain portions of its requirements for serving documents containing business proprietary information, until further notice.[15]

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to Commerce within 30 days of the date of publication of this notice.[16] Requests should contain: (1) The party's name, address, the telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held.[17] Parties are reminded that all briefs and hearing requests must be filed electronically using ACCESS and received successfully in their entirety by 5:00 p.m. Eastern Time on the due date.

Commerce intends to issue the final results of this administrative review, which will include the results of our analysis of all issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, unless extended, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results of this review, Commerce will determine, and CBP will assess, antidumping duties on all appropriate entries covered by this review.[18] Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication). Pursuant to Commerce's practice in NME cases, if we continue to determine in the final results that Comfort Coil had no

[4] Based on a recommendation by CBP, on September 6, 2017, Commerce added HTS 7326.20.0090 to the scope. *See* Memorandum, ''Request from Customs and Border Protection to Updated the ACE AD/CVD Case Reference File, Uncovered Innersprings from the People's Republic of China (A–570–928) and South Africa (A–791–821),'' dated September 6, 2017.

[5] *See* Memorandum, ''U.S. Customs and Border Protection Data Query,'' dated April 23, 2021.

[6] *Id.* at Attachment 1.

[7] *See* Comfort Coil's Letter, ''Uncovered Innerspring Units from the People's Republic of China—No Sales Certification,'' dated April 27, 2021.

[8] *See* Memorandum, ''Uncovered Innerspring Units from the People's Republic of China (A–570–928); No shipment inquiry with respect to Comfort Coil Technology Sdn. Bhd., during the period 02/01/2020 through 01/31/2021,'' dated August 10, 2021. After the initial release of the CBP data, the petitioner requested that Commerce issue its standard questionnaire to Comfort Coil, despite the CBP data revealing no POR shipments of subject merchandise. *See* Petitioner's Letter, ''Uncovered Innerspring Units from the People's Republic of China: Comments on US Customs and Border Protection Entry Data Results,'' dated April 30, 2021. However, absent record evidence from CBP (or any other source) calling into question the initial entry data, or the results of the subsequent no-shipment inquiry to CBP, there is no basis to issue the antidumping duty questionnaire to Comfort Coil here. Moreover, and as noted below, Commerce will complete the review with respect to Comfort Coil.

[9] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65694–95 (October 24, 2011); *see also* the ''Assessment Rates'' section, below.

[10] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[11] *See Order,* 74 FR at 7662.

[12] *See* 19 CFR 351.309(c)(1)(ii).

[13] *See* 19 CFR 351.309(d)(1) and (2); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

[14] *See* 19 CFR 351.309(c) and (d); *see also* 19 CFR 351.303 (for general filing requirements).

[15] *See Temporary Rule.*

[16] *See* 19 CFR 351.310(c).

[17] *See* 19 CFR 310(d).

[18] *See* 19 CFR 351.212(b)(1).

shipments of subject merchandise, any suspended entries of subject merchandise during the POR from Comfort Coil will be liquidated at the China-wide rate, 234.51 percent.[19]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of review, as provided for by section 751(a)(2)(C) of the Act: (1) For previously investigated or reviewed Chinese and non-Chinese exporters who are not under review in this segment of the proceeding but who have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (2) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be China-wide rate of 234.51 percent; and (3) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to Chinese exporter(s) that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

These preliminary results of review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: November 1, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–24227 Filed 11–4–21; 8:45 am]

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[19] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011); and *Order,* 74 FR at 7662.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–141]

Certain Walk-Behind Snow Throwers and Parts Thereof From the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that certain walk-behind snow throwers and parts thereof (snow throwers) from the People's Republic of China (China) are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is July 1, 2020, through December 31, 2020. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable November 5, 2021.

FOR FURTHER INFORMATION CONTACT: Laurel LaCivita or Brendan Quinn, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4243 or (202) 482–5848, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on April 26, 2021.[1] On August 20, 2021, Commerce postponed the preliminary determination of this investigation, and the revised deadline is now October 26, 2021.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The products covered by this investigation are snow throwers from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] MTD Products Inc. (the petitioner) commented on the scope of the investigation, requesting the addition of exclusion language to the scope as it appeared in the *Initiation Notice*.[6] Thus, Commerce preliminarily modified the scope language as it appeared in the *Initiation Notice* to include the requested language in the companion countervailing duty (CVD) preliminary determination.[7] *See* the revised scope in Appendix I to this notice and accompanying Preliminary Decision Memorandum for further discussion.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Because China is a non-market economy, within the meaning of section 771(18) of the Act, Commerce has calculated normal value in accordance with section 773(c) of the Act. In addition, pursuant to sections 776(a) and (b) of the Act,

[1] *See Certain Walk-Behind Snow Throwers and Parts Thereof from the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 86 FR 22026 (April 26, 2021) (*Initiation Notice*).

[2] *See Certain Walk-Behind Snow Throwers and Parts Thereof from the People's Republic of China: Postponement of Preliminary Determination in the Less-Than-Fair-Value Investigation,* 86 FR 46825 (August 20, 2021).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Certain Walk-Behind Snow Throwers and Parts Thereof from the People's Republic of China,'' dated concurrently with, and hereby adopted by this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice*, 86 FR at 22027.

[6] *See* Petitioner's Letter, ''Antidumping and Countervailing Duty Investigations of Certain Walk-Behind Snow Throwers from the People's Republic of China: Scope Comments,'' dated May 10, 2021.

[7] *See Certain Walk-Behind Snow Throwers and Parts Thereof from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Duty Determination,* 86 FR 50696, 50698 (September 10, 2021).

Commerce preliminarily has relied upon facts otherwise available, with adverse inferences, for the China-wide entity. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Combination Rates

In the *Initiation Notice,* Commerce stated that it would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation.[8] Policy Bulletin 05.1 describes this practice.[9] In this investigation, we calculated producer/exporter combination rates for respondents eligible for separate rates.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Zhejiang Zhouli Industrial Co., Ltd	Zhejiang Zhouli Industrial Co., Ltd	233.41	222.87
Ningbo Scojet Import & Export Trade Co., Ltd	Ninghai Yiyi Garden Tools Co., Ltd	233.41	222.87
Sumec Hardware and Tools Co., Ltd	Zhejiang KC Mechanical & Electrical Co., Ltd	233.41	222.87
Zhejiang Amerisun Technology Co., Ltd	Zhejiang Dobest Power Tools Co., Ltd	233.41	222.87
Zhejiang KC Mechanical & Electrical Co., Ltd	Zhejiang KC Mechanical & Electrical Co., Ltd	233.41	222.87
China-Wide Entity		325.03	314.49

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, as discussed below.

Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the weighted average amount by which normal value exceeds U.S. price, as indicated in the chart above as follows: (1) For the producer/exporter combinations listed in the table above, the cash deposit rate is equal to the estimated weighted-average dumping margin listed for that combination in the table; (2) for all combinations of Chinese producers/exporters of subject merchandise that have not established eligibility for their own separate rates, the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the China-wide entity; and (3) for all third-county exporters of subject merchandise not listed in the table above, the cash deposit rate is the cash deposit rate applicable to the Chinese producer/exporter combination (or the China-wide entity) that supplied that third-country exporter.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of domestic subsidy pass-through and export subsidies determined in a companion CVD proceeding when CVD provisional measures are in effect. Accordingly, where Commerce has made a preliminary affirmative determination for domestic subsidy pass-through or export subsidies, Commerce has offset the calculated estimated weighted-average dumping margin by the appropriate rate(s). Any such adjusted rates may be found in the chart of estimated weighted-average dumping margins in the ''Preliminary Determination'' section.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting cash deposits at a rate equal to the estimated weighted-average dumping margins calculated in this preliminary determination unadjusted for the passed-through domestic subsidies or for export subsidies at the time the CVD provisional measures expire. These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination. Normally, Commerce verifies information using standard procedures, including an on-site examination of original accounting, financial, and sales documentation. However, due to current travel restrictions in response to the global COVID–19 pandemic, Commerce is unable to conduct on-site verification in this investigation. Accordingly, we intend to verify the information relied upon in making the final determination through alternative means in lieu of an on-site verification.

Public Comment

Case briefs or other written comments on non-scope issues may be submitted to the Assistant Secretary for Enforcement and Compliance. A timeline for the submission of case briefs and written comments will be provided to interested parties at a later date. Rebuttal briefs, limited to issues raised in these case briefs, may be submitted no later than seven days after the deadline date for case briefs.[10] Note that Commerce has modified certain of its requirements for serving documents containing business proprietary information until further notice.[11] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are

[8] *See Initiation Notice,* 86 FR at 22030.

[9] *See* Policy Bulletin No. 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' (April 5, 2005) (Policy Bulletin 05.1), available on Commerce's website at *http://enforcement.trade.gov/policy/bull05-1.pdf.*

[10] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[11] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020) (*Temporary Rule*); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Additionally, interested parties may address the preliminary modification to the scope in scope case briefs, which may be submitted no later than 30 days after the publication of this preliminary determination in the **Federal Register**. Scope rebuttal briefs, limited to issues raised in the scope case briefs, may be submitted no later than seven days after the deadline for the scope case briefs. These deadlines apply for both the AD and CVD investigations of snow throwers from China.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On October 7, 2021, pursuant to 19 CFR 351.210(e), Zhejiang Zhouli Industrial Co., Ltd. requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[12] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) The preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination, pursuant to section 735(a)(2) of the Act.

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its preliminary determination of sales at LTFV. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of snow throwers from China are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: October 26, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, Performing the Non-Exclusive Functions and Duties of The Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation consists of gas-powered, walk-behind snow throwers (also known as snow blowers), which are snow moving machines that are powered by internal combustion engines and primarily pedestrian-controlled. The scope of the investigation covers certain snow throwers (also known as snow blowers), whether self-propelled or non-self-propelled, whether finished or unfinished, whether assembled or unassembled, and whether containing any additional features that provide for functions in addition to snow throwing. Subject merchandise also includes finished and unfinished snow throwers that are further processed in a third country or in the United States, including, but not limited to, assembly or any other processing that would not otherwise remove the merchandise from the scope of this investigation if performed in the country of manufacture of the in-scope snow throwers.

Walk-behind snow throwers subject to the scope of this investigation are powered by internal combustion engines which are typically spark ignition, single or multiple cylinder, and air-cooled with power take off shafts.

For the purposes of this investigation, an unfinished and/or unassembled snow thrower means at a minimum, a sub-assembly comprised of an engine, auger housing (*i.e.,* intake frame), and an auger (or ''auger paddle'') packaged or imported together. An intake frame is the portion of the snow thrower—typically of aluminum or steel—that houses and protects an operator from a rotating auger and is the intake point for the snow. Importation of the subassembly whether or not accompanied by, or attached to, additional components including, but not limited to, handle(s), impeller(s), chute(s), track tread(s), or wheel(s) constitutes an unfinished snow thrower for purposes of this investigation. The inclusion in a third country of any components other than the snow thrower sub-assembly does not remove the snow thrower from the scope. A snow thrower is within the scope of this investigation regardless of the origin of its engine.

Specifically excluded is merchandise covered by the scope of the antidumping and countervailing duty orders on certain vertical shaft engines between 225cc and 999cc, and parts thereof from the People's Republic of China. *See Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof, from the People's Republic of China: Amended Final Antidumping Duty Determination and Antidumping Duty Order,* 86 FR 12623 (March 4, 2021) and *Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China: Countervailing Duty Order and Amended Final Affirmative Countervailing Duty Determination,* 86 FR 12619 (March 4, 2021).

Also specifically excluded is merchandise covered by the scope of the antidumping and countervailing duty orders on certain vertical shaft engines between 99cc and Up to 225cc, and parts thereof from the People's Republic of China. *See Certain Vertical Shaft Engines Between 99cc and Up to 225cc, and Parts Thereof from the People's Republic of China: Antidumping and Countervailing Duty Orders,* 86 FR 023675 (May 4, 2021).

The snow throwers subject to this investigation are typically entered under Harmonized Tariff Schedule of the United States (HTSUS) subheading 8430.20.0060. Certain parts of snow throwers subject to this investigation may also enter under HTSUS 8431.49.9095. The HTSUS subheadings are provided for convenience and customs purposes only, and the written description of the merchandise under investigation is dispositive.

[12] *See* Zhejiang Zhouli's Letter, ''Certain Walk-Behind Snow Throwers and Parts Thereof from the People's Republic China: Request to Postpone the Final Determination,'' dated October 7, 2021.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2021–24226 Filed 11–4–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Decision on Applicationfor Duty-Free Entry of Scientific Instruments; Rice University, et al.

This is a decision pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, as amended by Pub. L. 106–36; 80 Stat. 897; 15 CFR part 301). On September 28, 2021,the Department of Commerce published a notice in the **Federal Register** requesting public comment on whether instruments of equivalent scientific value, for the purposes for which the instruments identified in the docket(s) below are intended to be used, are being manufactured in the United States. *See Application(s) for Duty-Free Entry of Scientific Instruments, 86 FR 53634 –35,September 28, 2021* (*Notice*). We received no public comments.

Docket Number: 21–001. *Applicant:* Rice University, 6100 Main Street, Houston, TX 77005. *Instrument:* LightCrafter 4500 EVM. *Manufacturer:* Digi-Key Electronics, China. *Intended Use:* The LightCrafter 4500 will be used in an ongoing research study to develop a compact optical mapping scope that uses Digital Light Processing (DLP) technology to capture white light and auto-fluorescence images and actively project onto the oral mucosa a map highlighting areas at high risk for oral dysplasia and cancer, based on: Loss of collagen fluorescence (a signal of invasion & metastasis) and alterations in epithelial NAD(P)H and FAD fluorescence (a signal of de-regulated cellular energetics). With this device, we will design and assemble an optical system that allows for wide field imaging of the oral cavity, where the LightCrafter 4500 is aligned with the camera such that any area that can be imaged can also be projected upon. We will develop tracking algorithms to adjust the projected map as needed to ensure accurate positioning despite patient movement. The objective is to develop an optical imaging system that will detect high-risk areas of the oral mucosa and project high-risk maps onto the oral mucosa to guide clinicians on where to take a biopsy.

Docket Number: 21–002. *Applicant:* Drexel University, 3401 Market Street, Philadelphia, PA 19104. *Instrument:* Light Microscope with motorized stage, attached camera and image—capturing hardware and software. *Manufacturer:* Info in Images Ltd., United Kingdom. *Intended Use:* To develop a novel research tool for scientists studying microscopic algae and to facilitate access to the holdings of the Diatom Herbarium at the Academy of Natural Sciences of Drexel University, a non-profit public museum with a mission of research in environmental conservation and public education. This customized automated microscope side-scanning system will be used to create high-resolution images of microscopic organisms on permanent slides that could be viewed and studied online using a virtual microscopy application. Digital images of the slides, containing millions of individual specimens of microorganisms and representing snapshots of their assemblages, will be served online to support research programs focused on environmental change and its effects on aquatic biota. The applications based on images acquired with this slide-scanning system will be used to increase the efficiency of water quality and ecosystem health monitoring in rivers, lakes, and coastal areas of the ocean.

Docket Number: 21–003. *Applicant:* UChicago Argonne LLC, Operator of Argonne National Laboratory, 9700 South Cass Avenue, Lemont, IL 60439–4873. *Instrument:* A:VC 19 Photon Extraction Vacuum Chambers. *Manufacturer:* Strumenti Scientific CINEL S.R.L., Italy. *Intended Use:* These components are required to complete the assembly of the Advanced Photon Source upgrade storage ring vacuum system. The APS–U storage ring vacuum system is approximately 1.1-km in circumference and will store the electron and photon beams in an ultra-high vacuum (UHV) environment. The materials/phenomena that are studied vary widely from material properties analysis, protein mapping for pharmaceutical companies, X-ray imaging and chemical composition determination, to name a few. These components will be used exclusively for scientific research for a minimum of 5 years at Argonne National Laboratory. The properties of the materials studied include but are not limited to grain structure, grain boundary and interstitial defects, and morphology. These properties are not only studied at ambient environments but also under high pressure, temperature, stress and strain. The objective is to further the understanding of different materials and material properties.

Docket Number: 21–004. *Applicant:* William Marsh Rice University, 6100 Main Street, Houston, TX 77005. *Instrument:* Angle-Resolved Photoemission Spectroscopy System. *Manufacturer:* Fermion Instruments, China. *Intended Use:* The technique of angle-resolved photoemission spectroscopy is a very specialized technique used to directly image the electronic structure of synthesized single crystalline materials or thin film materials. This technique is mainly used to study fundamental physical and electrical properties of materials, how electrons interact with each other leading to the insulating, metallic, or superconducting properties of materials for fundamental research. The measurement of electronic structure will provide important information on the fundamental physical origin of why a material is a good conductor or insulator or a superconductor. This will be beneficial towards new physics theories about solid state materials for academic purposes.

Docket Number: 21–005. *Applicant:* UChicago Argonne LLC, Operator of Argonne National Laboratory, 9700 South Cass Avenue, Lemont, IL 60439–4873. *Instrument:* POLAR Vertical Double Crystal Monochromator. *Manufacturer:* Strumenti Scientific CINEL, S.R.L., Italy. *Intended Use:* The instrument will be used as a monochromator for the Polar beamline at the Advanced Photon Source upgrade. The Polar beamline makes use of polarized synchrotron radiation to investigate magnetic properties of materials using a variety of spectroscopic and scattering methods. Materials investigated are scientific samples especially grown to answer specific scientific questions and to study basic magnetic and electric material properties. The device will be used exclusively for scientific research for a minimum of 5 years at Argonne National Laboratory. The objective is to further the understanding of material properties and to be able to tailor material properties to achieve specific magnetic and electron behavior.

Docket Number: 21–006. *Applicant:* Rutgers, The State University, 65 Davidson Road, Piscataway, NJ 00854. *Instrument:* SIPAT Crystal Grower JGD–

500–1 System. *Manufacturer:* Sipat Co., Ltd., Canada. *Intended Use:*The instruments will only be used for the study and basic understanding of the physical properties of oxide and/or metallic materials, various physical phenomena based on strongly correlated materials such as high temperature superconductors, Topological insulators, or Multiferroics. The growth of new materials will be conducted which have unique electric and magnetic properties using purchased crystal grower. To identify grown materials, we will employ x-ray diffraction and Laue. The high-quality crystals will be further investigated with a physical property measurement system and Magnetic property measurement system to obtain its electric and magnetic properties in varying conditions of temperature, electric and magnetic fields.

Docket Number: 21–007. *Applicant:* Oregon State University, 100 Wiegand Hall, 3051 SW Campus Way, Corvallis, OR 97331. *Instrument:* Radio Frequency Heating System. *Manufacturer:* FOSHAN JIYAN HIGH FREQUENCY EQUIP CO., LTD., China.Intended Use: The instrument will be used for studying the phenomena of radio frequency (FR) drying of food materials and understanding the effectiveness in comparison with conventional hot-air drying method. The objectives to be studied: (a) To investigate drying efficiency of radio frequency at various operation conditions and compare with conventional hot-air drying to reduce drying time/cost and improve product quality, (b) to evaluate radio frequency heating for other application in food processing, such as pasteurization, deshelling and roasting of nuts, and drying food processing byproducts. Analytical techniques will be used to obtain quantitative data from the experiments and analyzed statistically to draw valuable conclusions.

Docket Number: 21–008. *Applicant:* University of North Dakota, 266 Upson Hall II, 243 Centennial Drive, Grand Forks, ND 58202–8359. *Instrument:* Laser metal deposition system. *Manufacturer:* InssTek, South Korea. *Intended Use:* Materials to be used are elemental pure metal powders or alloyed metal powders, the research goal will be in-situ alloying of multiple different types of elemental powders (up to six) in the laser melting pool. The primary interest of materials is Inconel 625 alloy, which will be built using the in-situ alloying of commercially pure elemental powders, they are Cr, Mo, Nb, Fe, and Ni powders, and have the diameter ranging from 45 um to 150 um. After material is prepared, the energy-dispersive X-ray spectroscopy (EDS) will be used to analyze the chemical composition and elemental distribution, and the electron backscatter diffraction (EBSD) will be applied to observe the crystal orientation and grain structure. The objective is to broaden the material availability for AM and to explore its full potential.

Docket Number: 21–009. *Applicant:* Yale University, BCT326, 15 Prospect Street, New Haven, CT 06511. *Instrument:* 1.25W@4K G–M Cryocooler. *Manufacturer:* CSIC PRIDE (NANJING) CRYOGENIC TECHNOLOGY CO., China. *Intended Use:* The instrument will be used to research on superconducting films synthesized in our lab. These phenomena can only be brought to life when cooled to cryogenic temperatures created with liquid helium. The transition temperature (Tc) and magnetic susceptibility of our superconductor samples from the resistive normal state to the zero-resistance superconducting states will be measured. The instrument would slowly cool the sample to low temperature (4 K = −269° C) and measure its resistance and magnetic susceptibility at the same time to find the transition temperature Tc. This cryocooler will help to cool our sample from room temperature to 4 K, which is 269 °C below the freezing point in a controlled way. The cooling power required here is essential to ensure that we can reach and maintain at 4 K temperature. The small formfactor and vacuum-compatible design is also required for compatibility reasons.

Dated: November 1, 2021.

Richard Herring,

Director, Subsidies Enforcement, Enforcement and Compliance.

[FR Doc. 2021–24184 Filed 11–4–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–854]

Certain Steel Nails From Taiwan: Final Determination of No Shipments in the Antidumping Duty Administrative Review; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that Create Trading Co., Ltd. (Create Trading), the sole company under review, made no shipments of certain steel nails from Taiwan during the period of review (POR), July 1, 2019, to June 30, 2020.

DATES: Applicable November 5, 2021.

FOR FURTHER INFORMATION CONTACT: Irene Gorelik, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6905.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Determination* of the administrative review of certain steel nails from Taiwan on June 9, 2021.[1] The review covers one company, Create Trading Co., Ltd., which filed a statement of no sales.[2]

Scope of the Order [3]

The merchandise covered by this *Order* is certain steel nails from Taiwan. The certain steel nails subject to the *Order* are currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7317.00.55.02, 7317.00.55.03, 7317.00.55.05, 7317.00.55.07, 7317.00.55.08, 7317.00.55.11, 7317.00.55.18, 7317.00.55.19, 7317.00.55.20, 7317.00.55.30, 7317.00.55.40, 7317.00.55.50, 7317.00.55.60, 7317.00.55.70, 7317.00.55.80, 7317.00.55.90, 7317.00.65.30, 7317.00.65.60 and 7317.00.75.00. Certain steel nails subject to this *Order* also may be classified under HTSUS subheadings 7907.00.60.00, 8206.00.00.00 or other HTSUS subheadings. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this *Order* is dispositive. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.[4]

[1] *See Certain Steel Nails from Taiwan: Preliminary Determination of No Shipments in the Antidumping Duty Administrative Review;* 2019–2020, 86 FR 30590 (June 9, 2021) (*Preliminary Determination*).

[2] *See* Create Trading's Letter, ''Statement of No Sales to the United States,'' dated September 21, 2020. Specifically, Create Trading certified that all of its exports of subject merchandise were produced by unaffiliated producers that had knowledge of final destination to the United States at the time of sale to Create Trading, and thus, Create Trading certified that it has no reviewable sales for this POR.

[3] *See Certain Steel Nails from the Republic of Korea, Malaysia, the Sultanate of Oman, Taiwan, and the Socialist Republic of Vietnam: Antidumping Duty Orders,* 80 FR 39994 (July 13, 2015) (*Order*).

[4] *See* Memorandum, ''Issues and Decision Memorandum for the Final Determination of No

Continued

Analysis of Comments Received

In the Issues and Decision Memorandum, we address the sole issue raised in the case and rebuttal briefs submitted by interested parties. In the appendix to this notice, we provide a list of the topics discussed in the accompanying Issues and Decision Memorandum. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Determination of No Shipments

In the *Preliminary Determination,* Commerce determined that Create Trading had no shipments of subject merchandise during the POR.[5] As we have not received any information to contradict this determination, we continue to find that Create Trading had no shipments during the POR.

Assessment Rates

As discussed in the *Preliminary Determination,*[6] consistent with our reseller policy, we find it appropriate in this case to instruct U.S. Customs and Border Protection (CBP) to liquidate any existing entries of subject merchandise produced by Create Trading's unaffiliated producers and attributed to Create Trading at the rate applicable to the producer(s).[7] Because none of the producer(s) have their own rates, we will instruct CBP to liquidate entries at the all-others rate from the investigation, as revised, of 2.16 percent,[8] in accordance with the reseller policy.[9]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be in effect for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) For merchandise exported by manufacturers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment; (2) if the exporter is not a firm covered in a prior review, or the original investigation, but the manufacturer is, then the cash deposit rate will be the rate established for the most recently completed segment for the manufacturer of the merchandise; and (3) the cash deposit rate for all other manufacturers or exporters will continue to be 2.16 percent, the all-others cash deposit rate established in the *Amended LTFV Final.* These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers Regarding the Reimbursement of Duties

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as a final reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: November 1, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2021–24266 Filed 11–4–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Judges Panel of the Malcolm Baldrige National Quality Award

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of closed meeting.

SUMMARY: The Judges Panel of the Malcolm Baldrige National Quality Award (Judges Panel) will meet in closed session Monday, November 8, 2021 through Friday, November 12, 2021, from 10:00 a.m. until 5:00 p.m. Eastern Time each day. The purpose of this meeting is to review recommendations from site visits and recommend 2021 Malcolm Baldrige National Quality Award (Award) recipients. The meeting is closed to the public in order to protect the proprietary data to be examined and discussed at the meeting.

DATES: The meeting will be held Monday, November 8, 2021 through Friday, November 12, 2021, from 10:00 a.m. until 5:00 p.m. Eastern Time each day. The entire meeting will be closed to the public.

ADDRESSES: The meeting will be held virtually.

FOR FURTHER INFORMATION CONTACT: Robert Fangmeyer, Director, Baldrige Performance Excellence Program,

Shipments in the Antidumping Duty Administrative Review: Certain Steel Nails from Taiwan; 2019–2020,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[5] *See Preliminary Determination,* 86 FR at 30591.

[6] *Id.*

[7] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003) (*Assessment of Antidumping Duties*).

[8] The all-others rate from the underlying investigation was revised in *Certain Steel Nails from Taiwan: Notice of Court Decision Not in Harmony with Final Determination in Less than Fair Value Investigation and Notice of Amended Final Determination,* 82 FR 55090, 55091 (November 20, 2017) (*Amended LTFV Final*).

[9] *See Assessment of Antidumping Duties.*

National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 1020, Gaithersburg, MD 20899–1020, telephone number (301) 975–2361, email *robert.fangmeyer@nist.gov.*

SUPPLEMENTARY INFORMATION: *Authority:* 15 U.S.C. 3711a(d)(1) and the Federal Advisory Committee Act, as amended, 5 U.S.C. app.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. app., notice is hereby given that the Judges Panel will meet on Monday, November 8, 2021 through Friday, November 12, 2021, from 10:00 a.m. until 5:00 p.m. Eastern Time each day. The Judges Panel is composed of twelve members, appointed by the Secretary of Commerce, with balanced representation from U.S. service, manufacturing, nonprofit, education, and health care industries. Members are selected for their familiarity with quality improvement operations and competitiveness issues of manufacturing companies, service companies, small businesses, nonprofits, health care providers, and educational institutions. The purpose of this meeting is to review recommendations from site visits and recommend 2021 Award recipients. The meeting is closed to the public in order to protect the proprietary data to be examined and discussed at the meeting.

The Acting Chief Financial Officer and Assistant Secretary for Administration, with the concurrence of the Assistant General Counsel for Employment, Litigation, and Information, formally determined, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended by Section 5(c) of the Government in the Sunshine Act, Public Law 94–409, that the meeting of the Judges Panel may be closed to the public in accordance with 5 U.S.C. 552b(c)(4), because the meeting is likely to disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential; and 5 U.S.C. 552b(c)(9)(B) because the meeting is likely to disclose information the premature disclosure of which would, in the case of any agency, be likely to significantly frustrate implementation of a proposed agency action. The meeting, which involves examination of current Award applicant data from U.S. organizations and a discussion of these data as compared to the Award criteria in order to recommend Award recipients, will be closed to the public.

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2021–24280 Filed 11–4–21; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB569]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Groundfish Advisory Panel via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Monday, November 22, 2021, at 9:30 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/5432562027206901005.*

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Groundfish Advisory Panel will discuss draft alternatives and draft impacts analysis and make recommendations to the Groundfish Committee for Framework Adjustment 63 final action. The panel will make recommendations to the Committee, as appropriate, regarding possible 2022 Council priorities. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: November 1, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–24161 Filed 11–4–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB439]

Takes of Marine Mammals Incidental To Specified Activities; Taking Marine Mammals Incidental to the Palmer Station Pier Replacement Project, Antarctica

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 given that NMFS has issued an incidental harassment authorization (IHA) to the National Science Foundation (NSF) to incidentally harass, by Level B harassment and Level A harassment, marine mammals during pile driving activities associated with the construction of the Palmer Station Pier Replacement Project in Anvers Island, Antarctica.

DATES: This Authorization is effective from October 27, 2021 through October 26, 2022.

FOR FURTHER INFORMATION CONTACT: Robert Pauline, 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. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

Summary of Request

On December 29, 2020, NMFS received a request from the National Science Foundation (NSF) for an IHA to take marine mammals incidental to pile driving activities associated with the construction of the Palmer Station Pier Replacement Project on Anvers Island, Antarctica. Hereafter (unless otherwise specified) the term ''pile driving'' is used to refer to both pile installation (including DTH pile installation) and pile removal. NSF submitted several revisions of the application until it was deemed adequate and complete on July 15, 2021. NSF had requested, and NMFS has authorized, take of a small number of 17 species of marine mammals by Level B harassment and/or Level A harassment. Neither NSF nor NMFS expects serious injury or mortality to result from this activity, nor did NMFS authorize any. Therefore, an IHA is appropriate.

Description of Specified Activity

Overview

The purpose of the project is to construct a replacement pier at Palmer Station on Anvers Island, Antarctica for the United States Antarctic Program. It is severely deteriorated, and needs to be replaced as soon as possible. This project will include construction of a new steel pipe pile supported concrete deck pier, new modern energy absorbing fender system and on-site power and lighting. Construction of the replacement pier and removal of the existing pier will require down-the-hole (DTH) pile installation, vibratory hammer pile removal, vibratory hammer pile installation, limited impact driving to seat piles, rock chipping, and the use of a hydrogrinder. The planned project is expected to take up to 89 days of in-water work and will include the installation of 52 piles and removal of 36 piles. Due to a delay in schedule, in-water construction will now not begin until February 2, 2022 and will be completed no later than July 31, 2022. The **Federal Register** notification of the proposed IHA (86 FR 46199: August 18, 2021) stated that in-water construction would begin in October or November 2021, and would be completed by mid-April 2022. A detailed description of NSF's activities is provided in the **Federal Register** notification of the proposed IHA (86 FR 46199: August 18, 2021). The number of active construction days has not changed and no changes have been made to the planned construction activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specific activity.

Comments and Responses

A notice of NMFS' proposal to issue an IHA to NSF was published in the **Federal Register** on August 18, 2021 (86 FR 46199). That notice described, in detail, NSF'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 comments from Ari Friedlaender Ph.D., Institute of Marine Sciences, University of California, Santa Cruz. A summary of the commenter's recommendations as well as NMFS' responses is below. Please see Dr. Friedlaender's letter for full details regarding their recommendations and rationale. The letter is available online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.*

Comment 1. Dr. Friedlaender commented that several of the proposed take requests for marine mammals were based on inaccuracies and did not align with basic information on the distribution and abundance of animals around Palmer Station. He did not believe that the best available information was utilized. Dr. Friedlaender cited several research articles which were not contained in the **Federal Register** notification of the proposed IHA, which he felt could be useful in determining take of marine mammals.

Response: NMFS strives to identify and utilize the best available scientific information when evaluating potential impacts to marine mammals associated with actions described in submitted IHA applications. Dr. Friedlaender specifically identified papers by Felix *et al.* (2021), Johnston *et al.* (2012), and Jackson *et al.* (2006), as being relevant but were not included in the **Federal Register** notification of the proposed IHA.

Dr. Friedlaender commented that Felix *et al.* (2021) provided population estimates of 11,784 and 11,786 (up from 9,484 in the proposed IHA) for the breeding stock of humpback whales (breeding stock G) found in the vicinity of Palmer Station which constitutes about 90 percent of the humpback whale around the Antarctic Peninsula. Other stocks make up the remaining and are represented by approximately 10 percent of the Antarctic Peninsula abundance as presented by Reilly *et al.* (2004). This is considered to be the best available science and, therefore, NMFS has updated Table 1 and Table 17 in this notification of issuance to reflect the change.

NSF inadvertently omitted the paper by Johnston *et al.* (2012) from the application. Specifically, due to a word-processing formatting error the reference was not included in Table 6–3 of the application, although data from that source was used for the humpback whale group size estimate in the proposed IHA. The reference has been included in this notice. The density for humpback whales referenced in the Johnston *et al.* (2012) paper for Gerlach Strait in the area where Hero Inlet is located, is 0.09 whales/square kilometer (km^2) while the density used in the proposed IHA was 0.03 whales/km^2 (Santora *et al.,* 2009). Employing the density of 0.09 whales/km^2 to estimate takes provides a new Level A harassment take estimate for humpback whales of 14.74 (previously 5.91) and a new Level B harassment take estimate of 302.18 (previously 121.21) for a total estimate of 317 takes.

After the public comment period ended on September 17, Dr. Friedlaender provided additional data to NMFS that was collected over a 5-year period at Palmer Station from January 4, 2015 through March 18, 2020 (Friedlaender, Personal Communication). Unless otherwise noted, personal communications from Friedlaender were either with NSF (which NSF then shared with NMFS) or with NMFS. The data was collected between January and March/April of each year from small boats, unmanned aerial systems (UASs) and land-based surveys. Ninety percent of the surveys (424 of 471) took place within the Palmer Station small boating limits which covers waters out to 2.5 mi (4 km) from the Station. A small number of surveys took place within the extended small boating limits which extend out to 25 mi (40 km) from the Station. Up to 3 surveys were conducted per day. A total of 671 humpback whales were sighted between January and March or April over 5 years, which is an average of 33.4 animals per month. If it were assumed that the months of December and November also had the same average per month, then the total estimated take for the planned November–April work period would suggest 200 animals per year might be encountered in the area. However, to be precautionary, NMFS has used the Johnston *et al.* (2012) data to authorize 15 takes by Level A harassment and 302 takes by Level B harassment for a total of 317 authorized takes.

The paper by Jackson *et al.* (2006) does not provide abundance information on breeding stock G. Only breeding stocks E and F are included in this analysis. Therefore, it was not included as a reference for estimating humpback whale abundance near the Project Area.

NMFS will continue to use the best available scientific information, and 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 potentially impacted by incidental take authorizations.

Comment 2: Dr. Friedlaender questioned the source of the marine mammal observation data supplied by NSF from Hero Inlet and nearby areas. He indicated that the data does not represent the known dedicated marine mammal surveys that have been conducted as part of NSF's Long Term Ecological Research (LTER) program since 2015 in this exact area. He feels that such information could have provided for a more accurate assessment of species abundance and occurrence patterns. He noted that these data would demonstrate that the densities of both Antarctic minke whales and fin whales are not significantly larger than those of humpback whales near Palmer Station as was described in the notification of proposed IHA. Therefore, proposed take for minke and fin whales should not be higher than for humpback whales.

Response: The LTER data provided by Friedlaender over five years and 369 days worth of effort showed sightings of 671 humpback whales, 54 Antarctic minke whales, 5 killer whales, 1 southern right whale, zero blue whales, zero fin whales, 437 Antarctic fur seals, 22 leopard seals, 6 crabeater seals, 4 Weddell seals, and 2 southern elephant seals. Given this new information, NMFS agrees that estimates of takes for Antarctic minke whales (327) and fin whales (296) are likely overestimates of what may actually occur. The difference between is likely due to how available density estimates were appropriated. As part of the analysis in the proposed IHA if two density estimates (nearshore vs. offshore) for a marine mammal population are available, NMFS used the higher of two densities to be precautionary when estimating potential takes. As described in the notification of the proposed IHA, the nearshore density estimates for fin whales are significantly overestimated for Palmer Station as the density estimates come from surveys (Santora *et al.,* 2009) that occurred in depths that favored the nearshore distribution of fin whales in that specific area. It was also noted in the notification of the proposed IHA that fin whales have not been visually observed from Palmer Station during recent years. While approximately 5 Antarctic minke whale observations were recorded each year by Friedlaendar, the higher offshore density was also used to estimate take for Antarctic minke whales. Friedlaendar asserted that the proposed total takes of minke whales (327) and fin whales (296) should not be significantly higher than those of humpback whales (127). As noted in the previous comment, takes of humpback whales have been revised based on Johnston *et al.* (2021) data and are now (317) and authorized take of Antarctica minke whales (327) and fin whales (296) are no longer significantly higher. The takes that were proposed and are now authorized represent a precautionary approach to balance the estimated takes based solely on density and the observation data which recorded lower sightings.

In the absence of any additional data, NMFS has authorized take of minke whales and fin whales at the same levels that were determined in our preliminary findings in the **Federal Register** notification of the proposed IHA.

A student from Dr. Friedlaendar's lab provided raw data regarding pinniped observations near Palmer station. The data was being used as part of the graduate student's thesis. However, the data only covered a January to March time period and observations were taken over an area larger area than the Level A or Level B harassment zones. Therefore, the data was not used.

Comment 3: Dr. Friedlaender commented that it was difficult to comprehend how the Level A and Level B harassment zones were calculated. He provided an example of how the area of a circle demarcated by the radius of the harassment zone isopleth should be split in half since the coast of Anvers Island precludes 180-degrees of land leaving 180-degrees of water ensonified.

Response: The estimated areas (km^2) that would be ensonified above Level A and Level B harassment thresholds for each activity were calculated using the distances from Palmer Pier to the harassment thresholds for each species. The ensonified areas were determined by plotting these isopleths and using GIS to calculate the area within the polygons that would be above each threshold level. However, Palmer Pier is located in a narrow portion of Hero Inlet and the area potentially ensonified above Level A and Level B harassment thresholds is truncated by the proximity to land masses in the inlet (*i.e.,* shadow effect). In other words, acoustic propagation from the source would be impeded by natural features in the water, resulting in acoustic shadows behind such features. The areas of truncated land forms were subtracted from the combined circular land and water areas to calculate the in-water areas (*i.e.,* harassment zones) that are ensonified to Level A and Level B harassment thresholds. Therefore, no changes are necessary.

Comment 4: Dr. Friedlaender expressed concern that the required real-time monitoring methods seem inadequate and that animals occurring in a specified shutdown zone would not be detected. From personal experience in the region, he indicated that surveying the harassment zones from a single platform at Palmer Station, while likely to allow for seeing large marine mammals, would result in pinnipeds and small cetaceans (*e.g.,* minke whales) being missed by protected species observers (PSOs). He also suggested using unmanned aerial systems (UAS) and placing (PSOs) on nearby islands, in small boats.

Response: As part of the proposed IHA, NMFS considered some of Dr.

Friedlaender's concerns about the efficacy of monitoring the large Level A and Level B harassment zones from a location at the lab behind the pier construction site and we specifically sought additional public input on this topic. Regarding the suggestion to employ UASs, NMFS asked NSF if this was possible. NSF indicated that operations in Antarctica are currently highly restricted due to COVID [protocols]. As Palmer Station will be staffed (at maximum capacity [in accordance to COVID protocols]) for construction only, rather than science operations, it will not have the usual services and staff available to support scientific operations (*e.g.,* UAS operations, etc.). UAS operations in Antarctica are governed by the Antarctic Treaty and Protocol on Environmental Protection to the Antarctic Treaty, including domestic laws and regulations implementing its requirements, such as the Antarctic Conservation Act (ACA, 16 U.S.C. 2401 *et seq.*). Accordingly, the use of UAS requires experienced operators as well as an ACA waste permit (45 CFR part 671). Due to the limited staff capacity and thus lack of experienced operators, NSF did not obtain the necessary ACA waste permit. Given these circumstances, NMFS concurred with NSF's determination that this measure is not practicable. Regarding the placement of PSOs on islands in the vicinity of Palmer Station, due to life-safety and logistics issues, NSF has determined, and NMFS agrees, that it would not be practicable. Such an arrangement would require frequent small boat excursions each day, placing the boat operators and PSOs at risk. Given the extreme environment in Antarctica, weather can change drastically in minutes to an hour, potentially leaving PSOs stranded on an island for extended periods and putting them at risk.

Furthermore, this will not be a typical year at Palmer Station due to the construction of the new pier and will not be staffed as during a normal year. Palmer Station will be staffed to support construction activities, not small boating operations. The current pier will be demolished in order to build the new one. The normal launch area for small boating operations will be in the construction zone and any launching of small boats would be extremely difficult and dangerous. NSF will also not have the staff capacity or expertise that would be necessary to transport PSOs to islands or run frequent small boat operations.

Due to the size of some of the larger harassment zones, NMFS acknowledges that the entirety of the shutdown zones in the proposed IHA may not be fully visible to PSOs, especially for smaller marine mammals. However, NMFS concurs with NSF that the suggested monitoring and mitigation measures suggested by Dr. Friedlaender to extend the detection range are not practicable at this time. Accordingly, NMFS has reduced the shutdown zones (as described in Tables 18 and 19) in all instances where the shutdown zones specified in the notification of proposed IHA were greater than 1,000 m. This will allow PSO's to monitor the shutdown zones with greater efficacy. Animals that are observed beyond 1,000-m zones during authorized activities will be recorded as having been potentially taken by Level A harassment if they are located within the specified Level A harassment zone for that species. NMFS will also require NSF to document any marine mammals observed within these Level A harassment zones, to the extent practicable (noting that some distances to these zones are too large to fully observe). Note that the take estimates provided in both the notification of proposed IHA and the final IHA were derived assuming that there was no monitoring or mitigation. Given the logistical and safety challenges present at Palmer Station, NSF believes that the required monitoring measures will allow PSOs to adequately observe specified shutdown and harassment zones. NMFS agrees with this assessment.

Changes From the Proposed IHA to Final IHA

Table 4 in the notification of proposed IHA incorrectly listed the humpback whale as being Endangered under the Endangered Species Act and Depleted under the Marine Mammal Protection Act. Those attributes have been removed as shown in Table 1 in this notice. The reference for the Johnston *et al.* (2012) paper on humpback whales was inadvertently omitted from Table 6–3 in the application, although data on humpback whale group size was actually included in that table. Based on the recommendation from Dr. Friedlaender to use density findings from Johnston *et al.,* (2012), NMFS has utilized the revised humpback whale density (0.09 animals/km^2) resulting in increases of authorized take by both Level A and Level B harassment. These changes are described in more detail in the response to Comment 1. Recent humpback whale abundance data from Felix *et al.* (2021) was incorporated into this notice of issuance and is also described in detail in the response to Comment 1. Several of the species abundance estimates contained in Table 3 in the proposed IHA were incorrect. As such, abundance estimates for Antarctic minke whale, fin whale, and Southern elephant seal have been revised. Revisions to Antarctic minke whale and fin whale abundances were necessary since the estimates reported Reilly *et al.* (2004) in the proposed IHA (18,125 Antarctic minke whales and 4,672 fin whales) were based on a survey area that included both the Antarctic Peninsula and the Scotia Sea. The changes included in this notice (7,395 Antarctic minke whales and 1,492 fin whales) include data from only the Antarctic Peninsula survey area which is more representative of animal abundance near the Project Area. The abundance estimate published in the proposed IHA for Southern elephant seals (401,572) was incorrect. The actual abundance estimate is 413,671 according to Hindell *et al.* (2016).

NMFS had incorrectly listed only one proposed take of leopard seal by Level B harassment in Table 20 of the **Federal Register** notification of proposed IHA. The text clearly indicates that NMFS was proposing five takes by Level B harassment, in addition to the five authorized takes by Level A harassment. However, as described below authorized take of leopard seals has been increased above those presented in the notification of proposed IHA. These updates are based on the new in-water project schedule starting on February 2, 2022 and extending to July 31, 2022. The original schedule contained in the notification of proposed IHA had the project running from October/November through April. Also, the observational data submitted to NMFS that was used to develop pinniped take estimates was found to contain errors. NMFS requested that NSF submit the correct data and reassessed the pinniped take estimates for this notice. Revisions are described in the detail in the section *Marine Mammal Occurrence and Take Estimation.*

In cases where species' abundance estimates have changed the corresponding percentage of stock potentially affected has also been revised. Species where the percentages changed include humpback whale (from 1.34 to 2.69), Antarctic minke whale (from 1.80 to 4.42), and fin whale (from 6.33 to 19.84). Take revisions based on a reassessment of the corrected pinniped observational data resulted in increases in percentage of stock potentially taken for Southern elephant seals (from <0.01 to 0.23), Antarctic fur seals (0.02 to 0.05), Weddell seals (from 0.04 to 0.05), and Leopard seals (from <0.01 to 0.06). These revisions are

included in Table 17 of this notice. Finally, NMFS will now require the implementation and monitoring of a 1,000-m shutdown zone in every instance where the specified shutdown zone for a hearing group for a given activity was originally proposed to be greater than 1,000 m.

Description of Marine Mammals in the Area of Specified Activities

There are 17 species in the Project Area for which NMFS has authorized take. Sections 3 and 4 of NSF's 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' 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 1 lists all species or stocks for which take has been authorized, and summarizes best available information on the population or stock, including regulatory status under the MMPA and Endangered Species Act. For taxonomy, we follow Committee on Taxonomy (2020). Marine mammals in the Project Area do not constitute stocks under U.S. jurisdiction; therefore, there are no stock assessment reports. Additional information on these species may be found in Section 3 of NSF's application.

For species occurring near the Antarctic Peninsula the International Union for the Conservation of Nature (IUCN) status is provided. The IUCN systematically assesses the relative risk of extinction for terrestrial and aquatic plant and animal species via a classification scheme using five designations, including three threatened categories (Critically Endangered, Endangered, and Vulnerable) and two non-threatened categories (Near Threatened and Least Concern) (*www.iucnredlist.org/;* accessed June 10, 2021). These assessments are generally made relative to the species' global status, and therefore may have limited applicability when marine mammal stocks are defined because we analyze the potential population-level effects of the specified activity to the relevant stock. However, where stocks are not defined, IUCN status can provide a useful reference.

TABLE 1—MARINE MAMMALS POTENTIALLY PRESENT IN THE VICINITY OF THE PROJECT AREA

Common name	Scientific name	Stock[2]	ESA/MMPA/ IUCN status[3]	Abundance (CV)[4]
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)				
Family Balaenidae (right whales):				
Southern right whale	*Eubalaena australis*		E/D/LC	[5] 1,755 (0.62)
Family Balaenopteridae (rorquals):				
Humpback whale	*Megaptera novaeangliae australis*		-/LC	[15] 12,486
Antarctic minke whale	*Balaenoptera bonaerensis*		-/NT	[5] 7,395 (0.36)
Fin whale	*B. physalus quoyi*		E/D/VU	[5] 1,492 (0.57)
Blue whale	*B. musculus musculus*		E/D/EN	[13] 1,700
Sei whale	*Balaenoptera borealis*		E/D/EN	[14] 626
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)				
Family Physeteridae:				
Sperm whale	*Physeter macrocephalus*		E/D/VU	[7] 12,069 (0.17)
Family Ziphiidae (beaked whales):				
Arnoux's beaked whale	*Berardius arnuxii*		/DD	unknown
Southern bottlenose whale	*Hyperoodon planifrons*		-/LC	[8] 53,743 (0.12)
Family Delphinidae:				
Hourglass dolphin	*Lagenorhynchus cruciger*		-/LC	[9] 144,300 (0.17)
Killer whale	*Orcinus orca*[1]		-/DD	[8] 24,790 (0.23)
Long-finned pilot whale	*Globicephala melas edwardii*		-/LC	[9] 200,000 (0.35)
Order Carnivora—Superfamily Pinnipedia				
Family Otariidae (eared seals and sea lions):				
Antarctic fur seal	*Arctocephalus gazella*	South Georgia ..	-/LC	[10] 2,700,000
Family Phocidae(earless seals):-				
Southern elephant seal	*Mirounga leonina*	South Georgia ..	-/LC	[11] 413,671
Weddell seal	*Leptonychotes weddellii*		-/LC	[12] 500,000–1,000,000
Crabeater seal	*Lobodon carcinophaga*		-/LC	[12] 5,000,000–10,000,000
Leopard seal	*Hydrurga leptonyx*		-/LC	[12] 222,000–440,000

[1] Three distinct forms of killer whale have been described from Antarctic waters; referred to as types A, B, and C, they are purported prey specialists on Antarctic minke whales, seals, and fish, respectively (Pitman and Ensor, 2003; Pitman *et al.,* 2010).

[2] For most species in the AMLR, stocks are not delineated and entries refer generally to individuals of the species occurring in the research area.

[3] 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. Any species listed under the ESA is automatically designated under the MMPA as depleted. IUCN status: Endangered (EN), Vulnerable (VU), Near Threatened (NT), Least Concern (LC), Data Deficient (DD).

[3] 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. Any species listed under the ESA is automatically designated under the MMPA as depleted. IUCN status: Endangered (EN), Vulnerable (VU), Near Threatened (NT), Least Concern (LC), Data Deficient (DD).

[4] CV is coefficient of variation. All abundance estimates, except for those from Reilly *et al.,*(2004) (right, humpback, minke, and fin whales), are for entire Southern Ocean (*i.e.,* waters south of 60°S) and not the smaller area comprising the Southwest Fisheries Science Center (SWFSC) research area.

[5] Abundance estimates reported in Reilly *et al.,*(2004) for the Commission for the Conservation of Antarctic Marine Living Resources (CCAMLR) survey area from 2000. This value has been revised to include abundance in only the Antarctic Peninsula and excluded the Scotia Sea as part of the Survey Area which was shown in the proposed IHA.

[6] Southern Ocean abundance estimate (Branch *et al.,* 2007).
[7] Southern Ocean abundance estimate (IWC, 2001 in Whitehead, 2002).
[8] Southern Ocean abundance estimate from circumpolar surveys covering 68 percent of waters south of 60°S from 1991–98 (Branch and Butterworth, 2001).
[9] Southern Ocean abundance estimate derived from surveys conducted from 1976–88 (Kasamatsu and Joyce, 1995).
[10] South Georgia abundance estimate; likely >95 percent of range-wide abundance (Forcada and Staniland, 2009). Genetic evidence shows two distinct population regions, likely descended from surviving post-sealing populations at South Georgia, Bouvetøya, and Kerguelen Islands (Wynen *et al.,* 2000; Forcada and Staniland, 2009). Individuals from the South Georgia population (including breeding populations at the South Orkney and South Shetland Islands, which are within the ARA) are likely to occur in the ARA.
[11] The abundance figure provided in the proposed IHA was incorrect. The correct abundance is included in this Table (Hindell *et al.,* 2016).
[12] Range-wide abundance estimates (Thomas and Terhune, 2009; Bengtson, 2009; Rogers, 2009).
[13] Southern Ocean abundance estimate (Branch *et al.,* 2007).
[14] South of 60°S from NOAA (2015).
[15] Felix *et al.,* 2021. Population estimate for the humpback whale Breeding Stock G (BSG), defined by feeding grounds around the Antarctic Peninsula. Approximately 90% of humpback whales in Antarctic Peninsula are from BSG (Friedlaender, Personal Communication). Approximately 10% of Antarctic Peninsula abundance from Reilly *et al.*)2004) represents remaining.

A detailed description of the species likely to be affected by the pile driving activities, including brief introductions to the species and relevant stocks as well as available information regarding population trends and threats, and information regarding local occurrence, were provided in the notice for the proposed IHA. Since that time, we are not aware of any changes in the status of these species and stocks. As noted previously, the term ''pile driving'' (unless otherwise specified) is used to refer to both pile installation (including DTH pile installation) and pile removal.

Therefore, detailed descriptions are not provided here. Please refer to that **Federal Register** notice for these descriptions.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

The **Federal Register** notification of the proposed IHA (86 FR 46199; August 18, 2021) included a discussion of the effects of anthropogenic noise on marine mammals and the potential effects of underwater noise from NSF's specified activities 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 proposed IHA. No new data is available that suggests the potential responses and impacts to marine mammals would differ from those discussed in the notification of the proposed IHA.

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. As noted above, some take estimates have changed since the proposed IHA, and those changes are described in the *Marine Mammal Occurrence and Take Estimation* section below.

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 will primarily be by Level B harassment, as use of the acoustic sources (*i.e.,* pile installation and removal equipment) has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result, primarily for mysticetes due to large PTS zones as well as for phocids and otariids due to haulouts in the vicinity of the Project Area. Auditory injury is unlikely to occur for high frequency or mid-frequency species. The required mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable.

As described previously, no mortality or serious injury 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 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 estimate.

Acoustic Thresholds

NMFS recommends the use of 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 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 120 dB re 1 µPa (rms) for continuous (*e.g.,* vibratory pile-driving, DTH) and above 160 dB re 1 µPa (rms) for non-explosive impulsive (*e.g.,* seismic airguns, impact pile driving) or intermittent (*e.g.,* scientific sonar) sources.

DTH pile installation includes drilling (non-impulsive sound) and hammering (impulsive sound) to penetrate rocky substrates (Denes *et al.,* 2016; Denes *et al.,* 2019; Reyff and Heyvaert 2019). DTH pile installation was initially thought to be a primarily non-impulsive noise source. However, Denes *et al.,*

(2019) concluded from a study conducted in Virginia, that DTH pile installation should also be characterized as impulsive based on Southall *et al.,* (2007), who stated that signals with a >3 dB difference in sound pressure level in a 0.035-second window compared to a 1-second window can be considered impulsive. Therefore, DTH pile installation is treated as both an impulsive and non-impulsive noise source. In order to evaluate Level A harassment, DTH pile installation activities are evaluated according to the impulsive criteria and using 160 dB rms. Level B harassment isopleths for DTH are determined by applying non-impulsive criteria and using the 120 dB rms threshold which is also used for vibratory driving. This approach ensures that the largest ranges to effect for both Level A and Level B harassment are accounted for in the take estimation process for DTH.

NSF's planned activity includes the use of continuous (vibratory hammer, DTH pile installation, hydrogrinder) and impulsive (impact pile driving, DTH pile installation) sources, and therefore the 120 and 160 dB re 1 μPa (rms) is/are 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). NSF's planned activity includes the use of impulsive (*i.e.* impact hammer, DTH pile installation) and non-impulsive (*i.e.,* vibratory hammer, DTH pile installation, rock chipping, hydrogrinder) sources.

These thresholds are provided in Table 2. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2018 Technical Guidance, which may be accessed at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 2—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 1μPa²s. 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 sound field in the Project Area is the existing background noise plus additional in-water construction noise from the planned project. Marine mammals are expected to be affected via sound generated by the primary components of the project (*i.e.,* DTH pile installation, vibratory pile removal, limited impact for proofing purpose, rock chipping and use of hydrogrinders).

The estimated sound source levels (SSL) proposed by NSF and utilized by NMFS in this assessment are described below and are shown in Table 3. Appendix A in the application discusses in detail the sound source levels for all planned equipment. Sound levels from pile installation used in NSF's application came from the Caltrans Compendium (2015) or are based on empirical data collected from other sites with similar conditions (*e.g.,* rock substrate where DTH driving would be used to install piles). NSF referenced two studies to arrive at SSLs for 24-in DTH pile installation. Noise studies from Kodiak ferry terminal (Denes *et al.,* 2016) and Skagway cruise ship terminal (Reyff and Heyvart, 2019; Reyff, 2020). Results are shown in Table 3. NMFS has developed DTH pile installation guidelines which contain recommendations for appropriate SSLs. NSF applied these recommendations for 36-in DTH pile installation. However, NSF proposed to use the DTH pile installation SSLs shown in Table 3, which, for 24-in DTH pile installation and 24-in sockets, are more conservative than those recommended by NMFS, and NMFS deemed this approach acceptable.

NSF determined the SSLs for rock chipping based on underwater sounds measured for concrete demolition. NSF examined two sets of data available during the demolition of the Tappan Zee Bridge (state of New York) pier structures. NSF also considered the results from another study conducted by the Washington State Department of Transportation (WSDOT). Results from that analysis are shown in Table 3.

The U.S. Navy has assessed sound levels of the use of a hydrogrinder through underwater measurements (U.S. Navy 2018). The Navy measurements were reported in 1/1-octave frequency bands from 125 to 8,000 Hz for the helmet position that was assumed to be 0.5 to 1 meter (m) from the hydraulic grinder operation. The overall unweighted sound level was computed to be 167.5 dB at 0.5 to 1 m. Source sound levels in this report are provided for 10-m distances. Since this is a point source of sound, spherical spreading 20 Log TL coefficient results in a source

sound level of 142 to 148 dB at 10 m (see Appendix A in the application). A value of 146 dB at 10 m has been used to estimate marine mammal take associated with these tools.

NSF assumed that installation of approximately one to two piles would occur over a 12-hour work day. To be precautionary in calculating isopleths, this application assumes two installation activities would occur simultaneously. For example, two 36-in piles installed simultaneously or one 36-in pile and one 24-in pile. Brief impact pile driving of about 10 strikes may be used to seat the piles. A likely approach to installing 36-in piles would be to use DTH to install two 36-in piles simultaneously; one 36-in pile would be installed to 20-ft socket depth while a second 36-in abutment pile would be installed to a 30-ft socket depth. The abutment piles require additional depth to support lateral loads and to provide side friction against ice uplift that could occur at the shoreline. It is also possible that both 36-in piles may be installed simultaneously to 20-ft socket.

Rock chipping may be required to level pile areas and would normally occur on the same day as DTH pile installation, if possible. If rock chipping is conducted separately from DTH pile installation, takes are accounted for by using the area ensonified during DTH pile installation to calculate takes. This precautionary approach overestimates takes that could occur if only rock chipping is conducted by itself. Rock chipping is considered to be an impulsive source.

Existing sheetpile will be removed through vibratory extraction. In some instances it may be necessary to remove piles by cutting them off at the mudline using underwater hand cutting tools. Such activity would occur on the same days as vibratory extraction. Cutting piles off at the mudline would result in less underwater noise than vibratory removal. To be precautionary, estimated marine mammal takes were calculated by assuming all piles were removed by vibratory extraction.

TABLE 3—SOUND SOURCE LEVELS

Activity	Measured sound levels [1]				Source
	Peak	RMS	SEL [2]	TL	
24-in Piles					
DTH pile installation	190	166	154	15	Denes *et al.,* (2016).
Vibratory Driving [4]	170	165	165	15	Caltrans (2015).
Impact Driving	195	181	168	15	Caltrans (2015).
36-in Piles					
DTH pile installation	194	166	164	15	The DTH sound source proxy of 164 dB SEL is from 42-in piles, Reyff (2020) and Denes *et al.,* (2019).
Vibratory Driving	180	170	170	15	Caltrans (2015).
Impact Driving	210	193	183	15	Caltrans (2015).
H Piles inserted in 24-in. Sockets					
DTH pile installation	190	166	154	15	Denes *et al.,* (2016).
Vibratory Driving	170	165	165	15	Caltrans (2015).
Impact Driving	195	180	170	15	Caltrans (2015).
Removal of 24-in Template Piles					
Vibratory Driving	170	165	165	15	Caltrans (2015).
Removal of Sheet Piles					
Vibratory Driving	175	160	160	15	Caltrans (2015).
Rock Chipping					
Hydraulic Breaker	197	184	175	22	Tappan Zee Bridge.[6] [7]
Anode Installation					
Hydro-grinder	.....	146	.....	20	U.S. Navy (2008).

[1] See Appendix A in application for references and discussion of all sound sources.
[2] SEL is single strike for impact driving and DTH pile installation. SEL for vibratory installation is per second.
[4] Includes removal of 24-in. piles.
[5] While it is possible the socket depth would be only 20 ft, this application assumes the greater depth to be precautionary.
[6] Reyff, J. 2018. Demolition of Existing Tappan Zee Bridge. Summary of Underwater Sound Measurements for Mechanical Demolition of Concrete Pile Caps at Piers 114 and 115, Circular Caisson at Pier 166, and Rectangular Caisson at Pier 170. To David Capobianco, New York State Thruway Authority. December 18, 2020.
[7] Reyff, J. 2018. Demolition of Existing Tappan Zee Bridge Subject: Summary of Underwater Sound Measurements for Mechanical Demolition of Ice Breakers at Piers 173 and 169. To Kristine Edwards, New York State Thruway Authority. January 10, 2018.

When the sound fields from two or more concurrent pile installation activities overlap, the decibel addition of continuous noise sources results in much larger zone sizes than a single source. Decibel addition is not a

consideration when sound fields do not overlap. The increased SLs potentially associated with two concurrent sources with overlapping sound fields are shown in Table 4 (WSDOT 2015). Decibel addition is only applicable to continuous sources. According to NMFS guidance the SL for continuous sounds from DTH pile installation is 166 dB regardless of the size of the pile. Under decibel addition, simultaneous DTH pile installation activities would use a SL of 169 (166 + 3) to derive the isopleth for the Level B harassment zone.

TABLE 4—SIMULTANEOUS SOURCE DECIBEL ADDITION

Hammer types	Difference in SSL	Level A harassment zones	Level B harassment zones
Vibratory, Impact	Any	Use impact zones	Use largest zone.
Impact, Impact	Any	Use zones for each pile size and number of strikes.	Use zone for each pile size.
Vibratory, Vibratory	0 or 1 dB	Add 3 dB to the higher source level	Add 3 dB to the higher source level.
	2 or 3 dB	Add 2 dB to the higher source level	Add 2 dB to the higher source level.
	4 to 9 dB	Add 1 dB to the higher source level	Add 1 dB to the higher source level.
	10 dB or more	Add 0 dB to the higher source level	Add 0 dB to the higher source level.

Level B Harassment Zones

Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater TL is:

$$TL = B * \text{Log10}(R1/R2),$$

where:

TL = transmission loss in dB
B = transmission loss coefficient; for practical spreading equals 15
R1 = the distance of the modeled SPL from the driven pile, and
R2 = the distance from the driven pile of the initial measurement

The recommended TL coefficient for most nearshore environments is the practical spreading value of 15. This value results in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions, which is the most appropriate assumption for NSF's planned activity in the absence of specific modelling. Level B harassment isopleths are shown in Table 11 and Table 12.

Level A Harassment Zones

When the NMFS Technical Guidance (2016) was published, in recognition of the fact that ensonified area/volume could be more technically challenging to predict because of the duration component in the new thresholds, we developed a User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to help predict takes. We note that because of some of the assumptions included in the methods used for these tools, we anticipate that isopleths produced are typically going to be overestimates of some degree, which may result in some degree of overestimate of Level A harassment take. However, these tools offer the best way to predict appropriate isopleths when more sophisticated 3D modeling methods are not available, and NMFS continues to develop ways to quantitatively refine these tools, and will qualitatively address the output where appropriate. For stationary sources such as those planned for this project, NMFS User Spreadsheet predicts the distance at which, if a marine mammal remained at that distance the whole duration of the activity, it would incur PTS. Inputs used in the User Spreadsheet, and the resulting isopleths are reported below. Tables 7, 8 and 9 show User inputs for single sound sources while Tables 10, 11, and 12 contain User inputs for simultaneous sources. The resulting Level A harassment isopleths for non-simultaneous activities and simultaneous activities are shown in Table 11 and Table 12 respectively. Level B harassment isopleths for simultaneous DTH pile installation utilize a 169 dB SL and corresponding isopleths are shown in Table 12. Note that strike numbers for DTH pile installation were derived by applying the duration required to drive a single pile (minutes), the number of piles driven per day, and the strike rate (average strikes per second) rates to arrive at the total number of strikes in a 24-hour period. A rate of 10 strikes per second was assumed.

TABLE 5—NMFS TECHNICAL GUIDANCE (2020) USER SPREADSHEET INPUTS TO CALCULATE PTS ISOPLETHS FOR NON-SIMULTANEOUS VIBRATORY PILE INSTALLATION ACTIVITIES AND HYDROGRINDING

	36-in (dock dock abutment)-in	RHIB fender piles 24-in	24-in template 10′ socket	24-in wave attenuator piles-in	24-in template pile removal	Sheet pile removal	Anode installation (hydro-grinding)
Spreadsheet Tab Used.	(A.1) Non-Impul, Stat, Cont.	(A.1) Non-Impul, Stat, Cont.	(A.1) Non-Impul, Stat, Cont.	(A.1) Non-Impul, Stat, Cont.	(A.1) Non-Impul, Stat, Cont.	(A.1) Non-Impul, Stat, Cont.	(A.1) Non-Impul, Stat, Cont.
Source Level (SPL RMS).	170	165	165	165	165	160	146.
15Transmission Loss Coefficient.	15	15	15	15	15	15	20.
Weighting Factor Adjustment (kHz).	2.5	2.5	2.5	2.5	2.5	2.5	2.5.
Time to install/remove single pile (minutes).	30	30	30	30	30	30	120.
Piles to install/remove per day.	1	1	2	1	16	16	1.

TABLE 6—NMFS TECHNICAL GUIDANCE (2020) USER SPREADSHEET INPUT TO CALCULATE PTS ISOPLETHS FOR NON-SIMULTANEOUS IMPACT PILE INSTALLATION ACTIVITIES

	36-in (dock, dock abutment)	24-in RHIB (template, wave attenuator)	Rock chipping
Spreadsheet Tab Used	(E.1) Impact pile driving	(E.1) Impact pile driving	(E) Stationary Source: Impulsive, Intermittent.
Source Level (Single Strike/shot SEL).	183	168	197.
Transmission Loss Coefficient	15	15	22.
Weighting Factor Adjustment (kHz)	2	2	0.
Number of pulses in 1-hr period	10	10	2,700.
Piles per day	1	1.	

TABLE 7—NMFS TECHNICAL GUIDANCE (2020) USER SPREADSHEET INPUT TO CALCULATE PTS ISOPLETHS FOR NON-SIMULTANEOUS DTH PILE INSTALLATION ACTIVITIES

	36-in dock 20′ socket	Dock abutment-36-in 30′ socket	24-in RHIB, template, wave attenuator
Spreadsheet Tab Used	(E.2) DTH Pile Driving	(E.2) DTH Pile Driving	(E.2) DTH Pile Driving.
Source Level (Single Strike/Shot SEL).	164	164	154.
Transmission Loss Coefficient	15	15	15.
Strike rate (Strikes/sec)	10	10	10.
Duration (min)	345	518	345.
Weighting Factor Adjustment (kHz)	2	2	2.
Strikes/pile	207,000	310,500	207,000.
Piles to install/remove per day	1	1	1.

TABLE 8—NMFS TECHNICAL GUIDANCE (2020) USER SPREADSHEET INPUT TO CALCULATE PTS ISOPLETHS FOR SIMULTANEOUS VIBRATORY PILE INSTALLATION ACTIVITIES

	36-in dock 20′ socket x 2 dock abutment	RHIB fender piles 24-in x 2	24-in template 10′ socket x 4	24-in wave attenuator piles-10′ socket x 2	24-in wave attenuator piles-20′ socket x 2
Spreadsheet Tab Used	(A.1) Non-Impul, Stat, Cont..	(A.1) Non-Impul, Stat, Cont..	(A.1) Non-Impul, Stat, Cont..	(A.1) Non-Impul, Stat, Cont..	(A.1) Non-Impul, Stat, Cont.
Source Level (SPL RMS)	173	168	168	168	168.
Transmission Loss Coefficient	15	15	15	15	15.
Weighting Factor Adjustment (kHz).	2.5	2.5	2.5	2.5	2.5.
Time to install/remove single pile (minutes).	30	30	15	30	30.
Piles to install/remove per day	2	2	4	2	2.

TABLE 9—NMFS TECHNICAL GUIDANCE (2020) USER SPREADSHEET INPUT TO CALCULATE PTS ISOPLETHS FOR SIMULTANEOUS IMPACT PILE INSTALLATION ACTIVITIES

	36-in (dock 20′ socket × 2) or dock abutment-36-in 30′ and 20′ socket	RHIB fender piles 24-in × 2	24-in template 10′ socket × 4	24-in wave attenuator piles × 2
Spreadsheet Tab Used	(E.1) Impact pile driving	(E.1) Impact pile driving	(E.1) Impact pile driving	(E.1) Impact pile driving.
Source Level (Single Strike/shot SEL).	183	168	168	168.
Transmission Loss Coefficient	15	15	15	15.
Weighting Factor Adjustment (kHz).	2	2	2	2.
Strikes/pile	10	10	10	10.
Piles per day	2	2	4	2.

TABLE 10—NMFS TECHNICAL GUIDANCE (2020) USER SPREADSHEET INPUT TO CALCULATE PTS ISOPLETHS FOR SIMULTANEOUS DTH PILE INSTALLATION ACTIVITIES

	36-in dock 20′ socket × 2	Dock abutment-36-in 30′ and 20′ socket	24-in template 10′ socket × 4	24-in wave attenuator piles-10′ socket × 2/RHIB fender piles 24-in × 2
Spreadsheet Tab Used	(E.2) DTH Pile Driving	(E.2) DTH Pile Driving	(E.2) DTH Pile Driving	(E.2) DTH Pile Driving.
Source Level (Single Strike/Shot SEL).	164	164	154	154.
Transmission Loss Coefficient	15	15	15	15.
Strike rate (Strikes/sec)	10	10	10	10.

TABLE 10—NMFS TECHNICAL GUIDANCE (2020) USER SPREADSHEET INPUT TO CALCULATE PTS ISOPLETHS FOR SIMULTANEOUS DTH PILE INSTALLATION ACTIVITIES—Continued

	36-in dock 20′ socket × 2	Dock abutment-36-in 30′ and 20′ socket	24-in template 10′ socket × 4	24-in wave attenuator piles-10′ socket × 2/RHIB fender piles 24-in × 2
Duration (min)	345	430	172.5	345.
Weighting Factor Adjustment (kHz).	2	2	2	2.
Strikes/pile	414,000	517,500	103,500	207,000.
Piles to install per day	2	2	4	2.

TABLE 11—LEVEL A AND LEVEL B HARASSMENT ISOPLETHS FOR NON-SIMULTANEOUS PILE INSTALLATION ACTIVITIES

		Level A harassment zones (m) based on SELcum					Level B harassment zone (m)
		Cetaceans			Pinnipeds		
		LF	MF	HF	PW	OW	
Dock, 36-in Dia. Pile Installation, 20′ Socket Depth—1 pile/day.	DTH Pile Drilling	1,891	67	2,253	1,012	74	11,659
Dock Abutment, 36-in Dia. Pile Installation, 30′ Socket Depth—1 pile/day.	DTH Pile Drilling	2,478	88	2,951	1,326	97	11,659
RHIB Fender Piles, 24-in Dia. Pile Installation, 20′ Socket—1 pile/day.	DTH Pile Drilling	407	15	485	218	16	11,659
24-in Dia. Template Piles, 10′ Socket Depth—2 piles/day	DTH Pile Drilling	407	15	485	218	16	11,659
24-in Dia. Wave Attenuator Piles, 20′ Socket Depth—1 pile/day.	DTH Pile Drilling	407	15	485	218	16	11,659
Retaining Wall HP Pile inserted in Drilled 24-in Dia. Sockets, 20′ Socket Depth—1 pile/day.	DTH Pile Drilling	407	15	485	218	16	11,659
Removal of 24-in Dia. Template Piles—16 piles	Vibratory	51	5	75	31	2	10,000
Removal of Sheet Piles	Vibratory	23	2	35	14	1	4,642
Rock Chipping/Floor Preparation	Hydraulic Breaker	403	50	716	204	29	123
Anode Installation	Hydrogrinder	1.9	0.3	2.5	1.3	0.2	200

TABLE 12 —LEVEL A AND LEVEL B HARASSMENT ISOPLETHS FOR SIMULTANEOUS PILE INSTALLATION ACTIVITIES

Daily activity scenario	Installation method	Level A harassment zones (m) based on SELcum					Level B harassment zone (m)
		Cetaceans			Pinnipeds		
		LF	MF	HF	PW	OW	
Dock, 36-in Dia. Pile Installation, 20′ Socket Depth—2 pile/day.	DTH Pile Installation	3,002	107	3,576	1,607	117	18,478
Dock Abutment, 36-in Dia. Pile Installation, 30′ Socket Depth and 36-in Dia. Pile 20′ Socket Depth.		3,484	124	4,149	1,864	136	18,478
RHIB Fender Piles, 24-in Dia. Pile Installation, 20′ Socket—2 pile/day.		647	23	770	346	25	18,478
24-in Dia. Template Piles, 10′ Socket Depth—4 piles/day.							
24-in Dia. Wave Attenuator Piles, 20′ Socket Depth—2 pile/day.							
Retaining Wall—HP Pile inserted in Drilled 24-in Dia. Sockets, 20′ Socket Depth—2 piles/day.							
Dock, 36-in Dia. Pile Installation, 20′ Socket Depth—1 pile/day and Wave Attenuator, 24-in Dia. Pile Installation, 20′ Socket—1 pile/day.		2,011	72	2,395	1,076	78	18,478
Dock 36-in Dia. Pile Installation 30′ Socket Depth and 24-in Dia. Pile Installation 20′ Socket Depth.		2,885	103	3,436	1,544	133	18,478
36-in Dock 20′ socket × 2 Dock Abutment	Vibratory Installation	43	4	64	26	2	34,146
RHIB Fender Piles 24-in × 2		20	2	30	12	1	15,849
24-in template 10′ socket 4.							
24-in wave attenuator piles-10′ socket × 2		31.8	3	47	19	1.4	
24-in wave attenuator piles-20′ socket × 2.							

The calculated area ensonified by single or multiple pile installation and removal sound sources is calculated based on the distance from the Palmer Station Pier installation location to the edge of the isopleth for Level B harassment and for each hearing group for Level A harassment. The scenario with the largest zone is used to estimate potential marine mammal exposures and those areas are shown in Table 13. The Palmer Station Pier is located in a narrow portion of Hero Inlet and the areas potentially ensonified above Level A and Level B harassment thresholds is truncated by the location of land masses including assorted islands (*i.e.,* shadow effect).

Table 12 shows the construction scenario (installation of two 36-in piles, one at 30- ft and a second at 20-ft socket depth) that results in the largest PTS zone isopleths while Table 13 shows the areas of the corresponding zones ensonified areas. The maximum Level A harassment distance would be 1,864 m (1.4 km^2) for phocids in water (PW), 3,484 m (3.38 km^2) for LF cetaceans, and 4,149 m (4.4 km^2) for HF cetaceans (although HF cetaceans are considered

rare in the Project Area and Level A harassment takes are not authorized). The largest Level B harassment isopleth is associated with simultaneous DTH pile installation and would be at a distance of 18,478 m from the source covering an area of 54.99 m.

TABLE 13—HARASSMENT ZONE AREAS USED FOR TAKE ESTIMATION [1]

Pile type	Total piles	Level A max area cetaceans [3] (km^2)	Level A max area pinnipeds [3] (km^2)	Level B area all species (km^2)
36-in piles (one @30-ft socket depth and one @20-ft socket depth).	18	3.38 (LF), 4.4 (HF), 0.03 (MF).	1.4 (PW), 0.03 (OW)	54.99
32-in piles (Bent 1)	4			
Pile Removal (24-in)	16	0.006 (LF), 0.012 (MF), ~0 (MF).	0.002 (PW)	20.78
Sheetpile Removal	20	0.001 (LF), 0.003 (HF), ~0 (MF).	0.0006 (PW)	5.27
Anode Installation	n/a	n/a	n/a	0.07
Rock Chipping	unk			
Total	88			

[1] Assumes simultaneous installation (*i.e.,* two pile installations occurring at the same time).

Marine Mammal Occurrence and Take Estimation

In this section we provide the information about the presence, density, or group dynamics of marine mammals that have informed the take calculations.

The approach by which the information provided above is brought together to produce a quantitative take estimate is described here. For marine mammals with known density information estimated harassment take numbers are calculated using the following equation (summed across each type of activity):

Estimated take = animal density × ensonified area × operating days

For some species observational data is also available and is used to estimate take. When both density and observational data are available for a given species, NMFS used the higher of the two values. NMFS used the most conservative option for estimating ensonified area for each activity as well as the most conservative estimates of the number of days of work for each activity. Note that the take estimates described below do not take mitigation and monitoring measures into account.

Takes were estimated by considering the density of marine mammals per km^2 multiplied by the potential area ensonified (km^2) and the number of days the noise could occur during in-water construction. The Project Area is located in the nearshore environment relative to the Antarctic Peninsula as defined by data reported in Santora *et al.* (2009). Sources for density data and average group sizes are found in Table 6–3 in the application.

Note that a reference for Johnston *et al.* (2012) regarding humpback whales was inadvertently omitted from Table 6–3 in the application. The reference was used to determine average humpback whale group size. Dr. Friedlaender recommended that the humpback whale density (0.09 animals/km^2) provided in that paper be used to estimate take of humpback whales. NMFS agrees with this revision and authorized take of humpback whales by both Level A and Level B harassment has been increased accordingly in this notification of issuance.

Regarding the application of the density data for the 17 species authorized for take, for some species only offshore data were available, for some only nearshore data, and for others data existed for both areas in which case we used the higher of the two values. Offshore densities were used to estimate take for eight species, nearshore data was used for five species and local observational data was used for four species. Data from these offshore sources results in averaging across large portions of the region. NSF notes that these data are from areas where cetaceans may occur in significantly greater densities than the Palmer Pier Project Area due to expected increased faunal density along the sea ice edge and shelf-frontal features in the southern oceans. These oceanographic features are not present within the Project Area, so lower densities of cetaceans are expected within close proximity to Palmer Station. Therefore, the offshore densities may represent an overestimate of anticipated densities within the Palmer Station Project Area.

NSF estimated Level A harassment takes by multiplying the Level A harassment areas by the species density (nearshore or offshore as described above) which was then multiplied by the expected number of pile driving days for each activity type. The exposures for each activity were added to arrive at calculated Level A harassment take number as shown in Table 14. In cases where both nearshore and offshore densities were available, the higher of the two densities is used to estimate take. A similar approach was employed to derive estimated take by Level B harassment. The Level B harassment zones are determined by taking the total area of the Level B harassment zones (54.99 km^2; 20.78 km^2; 5.27 km^2; 0.07 km^2) and subtracting the Level A harassment areas as defined by activity type and hearing group.

The Level B harassment zone area was multiplied by the highest density for a species (nearshore or offshore as described above) which was multiplied by the expected number of pile driving days for each activity type. The exposures for each activity were summed to arrive at the calculated Level B harassment take numbers as shown in Table 14. Additional detailed information may be found in Appendix B of the application.

TABLE 14—CALCULATED LEVEL A AND LEVEL B HARASSMENT EXPOSURES BASED ON DENSITY DATA

Species	Level A harassment total exposures	Level B harassment total exposures
Antarctic Minke Whale (LF)	15.23	312.25
Arnoux's Beaked Whale (MF)	0.0001	0.14
Blue Whale (LF)	0.0081	0.17
Fin Whale (LF)	13.74	281.70
Hourglass Dolphin (HF)	0.32	4.94
Humpback Whale (LF)	14.72	302.18
Killer Whale (MF)	0.04	111.70
Long-finned Pilot Whale (MF)	0.01	28.19
Southern Bottlenose Whale (MF)	0.009	23.55
Sei Whale (LF)	0.04	0.84
Southern Right Whale (LF)	0.07	1.34
Sperm Whale (MF)	0.02	16.73
Antarctic Fur Seal (OW)	0.15	356.50
Crabeater Seal (PW)	119.07	6128.78
Southern Elephant Seal (PW)	0.02	1.04
Leopard Seal (PW)	0.02	1.04
Weddell Seal (PW)	3.65	187.97

In addition to considering density data presented in the literature, recent marine mammal observation data taken by bird researchers from Hero Inlet and nearby areas was considered. Palmer Station's research support staff conducted wildlife observations over the course of 15 months, on an average of 23 days a month. Observations were made for six minutes, three times per day, at 8 a.m., 1 p.m. and 5 p.m. local time. The observer stood on the current pier to collect the observations. When weather conditions would not permit observations from the pier, observations were conducted from BioLab Building's second story located close behind the pier. The notification of proposed IHA contained an error that was included in NSF's IHA application. Table 19 in the notification of proposed IHA described how many pinnipeds had been observed at Palmer Station between the periods of January 21–March 28, 2019 and October 12, 2019–March 31, 2020. The column with the header October 12, 2019 through March 31, 2020 actually included data that was collected from March 30 to October 10, 2019. This time period was not included in Table 19 in the notification of proposed IHA. NMFS requested that NSF submit the corrected data for each of the three survey periods. The corrected table is included below as Table 15.

Table 15 shows a comparison between observational data from the Project Area (NSF, personal communication) and the calculated takes by Level A harassment based on density data.

TABLE 15—COMPARISON OF OBSERVATION DATA FROM HERO INLET, GAMAGE POINT AND BONAPARTE POINT 2019–2020 TO TOTAL LEVEL A HARASSMENT EXPOSURE ESTIMATES CALCULATED BASED ON DENSITY DATA

Species	January 21–March 28, 2019 observations	March 30–October 10, 2019 observations	October 12, 2019–March 2020 observations
Humpback Whale (LF)	0	0	2
Antarctic Fur Seal (OW)	73	70	241
Crabeater Seal (PW)	20	24	24
Southern Elephant Seal (PW)	1	0	278
Leopard Seal (PW)	3	2	2
Weddell Seal (PW)	8	6	39

As noted above, in relation to the observational data, NMFS has re-analyzed estimated take of pinniped species in consideration of NSF's modification of the project dates (the project schedule now runs from February, 2020 to July, 2020 instead of October/November, 2002 to April 2020) and the error in the pinniped observation data considered in the proposed IHA.

In consideration of all of the raw data across 20 months, given the short daily observation periods and the large variation in numbers (even within the same month of a different year), we elected to use the highest number of animals of a given pinniped species observed on a single day during any month of the year, and then to multiply this value by the number of planned in-water work days (89). Further, although pinniped density would typically be expected to be focused closer to shore, given potential limitations of NSF's observation methods, we elected to precautionarily increase these estimated take numbers by 50 percent. We compared the takes based on observational data to the take numbers derived from published density values (Table 14) and then authorized the larger of these two values. Density-derived takes were only greater for crabeater seals, so that is what we used in the final IHA and remains unchanged from the proposed IHA.

Regarding the estimation of take by Level A harassment, for species in which the observational data is used rather than density, we consider what proportion of the total take would appropriately, or conservatively, be expected be in the form of Level A harassment. The area ensonified above the Level A take threshold is very small compared to the area ensonified above the Level B harassment zone (Table 13)—specifically, less than 3% for the largest source and most sensitive taxa (phocids) and far smaller for other groups. Further, the implementation of shutdown zones is expected to avoid

some of the higher level or longer duration exposures that might potentially result in PTS. However, given that pinnipeds would be likely to spend a larger portion of their time in closer proximity to land (and potentially the pile driving source), we deemed it appropriate to conservatively estimate that 10 percent of the total calculated takes could potentially be by Level A harassment with the rest taken by Level B harassment.

Table 16 shows the maximum number of animals observed on a single day during any month as well as authorized takes by Level A harassment, Level B harassment and combined takes for each pinniped species. Total combined Level A harassment and Level B harassment takes have increased from 1 to 936 for southern elephant seals; from 437 to 1,335 for Antarctic fur seals; from 198 to 267 Weddell seals; and from 10 to 134 leopard seals. The density-based authorized take of crabeater seals remains unchanged at 6,249 from the notification of proposed IHA.

TABLE 16—FINAL AUTHORIZED TAKES BASED ON OBSERVATIONAL OR DENSITY DATA (WHICHEVER HIGHEST)

Species	Max # observed per day	Level A	Level B	Total (Level A + Level B)
Southern elephant seal	7	94	841	935
Antarctic fur seal	10	134	1,201	1,335
Weddell seal	2	27	240	267
Crabeater seal *	4	120	6,129	6,249
Leopard seal	1	14	120	134

* Based on Density Data.

Additional marine mammal observation data collected over a 5-year period at Palmer Station from January 4, 2015 through March 18, 2020 was also considered (Friedlaender, Personal Communication). The data was collected using small boats, unmanned aerial systems (UASs) and land-based surveys. The assessment of this data is described as part of the responses to Comment 1 and Comment 2.

Table 17 compares the number of calculated and authorized Level A and B harassment takes for each species. Level B harassment takes for Arnoux's beaked whale, blue whale, hourglass dolphin, sei whale, and Southern right whale have been adjusted based on group size such that a higher level of Level B harassment take has been authorized than was projected solely based on densities. Arnoux's beaked whales often occur in groups of 6–10 and occasionally up to 50 or more (Balcomb 1989). As a precautionary measure NSF requested and NMFS has authorized 12 takes of this species by Level B harassment. Classified as HF cetaceans, these beaked whales have a relatively large Level A harassment zone that extends to as much as 4,149 m. However, calculated take by Level A harassment is fractional and furthermore, this is a deep diving and deep foraging species and it would be unlikely that animals would congregate in a Level A harassment zone long enough to accrue enough energy to experience PTS. Therefore, no take by Level A harassment was requested, nor has been authorized by NMFS. Blue whales are unlikely to be found in the Project Area. However, NSF requested and NMFS has conservatively authorized two Level B harassment takes based on one average group size (NMFS, 2020). Hourglass dolphins group size is generally 2–6 individuals with groups of up to 25 observed (Santora 2012). Classified as HF cetaceans, these dolphins have a relatively large Level A harassment zone that extends to 4,149 m. However, local observational data sets have not recorded a single animal and the species tends to be found in waters close to the Antarctic Convergence. Given this information NMFS has authorized 25 takes by Level B harassment which is a reduction from 60 takes requested by NSF. Level A harassment takes are not expected or authorized since the dolphin species is highly mobile and is unlikely to remain in the zone long enough to experience PTS. Sei whales have an average group size of 6 (NMFS 2020) and generally inhabit continental shelf and slope waters far from coastlines. They are unlikely to occur, but as a precautionary measure, NSF had requested and NMFS has authorized 6 takes by Level B harassment. Takes by Level A harassment are not expected or authorized. Southern right whales live in groups of up to 20 individuals, but are more commonly found in groups of two or three, unless at feeding grounds. Observational surveys near Palmer Station did not record the presence of these whales. Therefore, NSF requested and NMFS has subsequently authorized 20 takes of Southern right whale by Level B harassment. No take by Level A harassment is anticipated or authorized.

TABLE 17—AUTHORIZED TAKES BY LEVEL A AND LEVEL B HARASSMENT AND AS A PERCENTAGE OF ABUNDANCE

Species	Authorized level A harassment take	Authorized level B harassment take	Total takes as percent of abundance
Antarctic Minke Whale (LF)	15	312	4.42
Arnoux's Beaked Whale (MF) [a]	0	12	Unknown
Blue Whale (LF) [a]	0	2	0.12
Fin Whale (LF)	14	282	19.84
Hourglass Dolphin (HF) [a]	0	25	0.02
Humpback Whale (LF)	15	302	2.54
Killer Whale (MF)	0	112	0.45
Long-finned Pilot Whale (MF)	0	28	0.01
Southern Bottlenose Whale (MF)	0	24	0.04
Sei Whale (LF) [a]	0	6	0.96
Southern Right Whale (LF) [a]	0	20	1.13
Sperm Whale (MF)	0	17	0.14

TABLE 17—AUTHORIZED TAKES BY LEVEL A AND LEVEL B HARASSMENT AND AS A PERCENTAGE OF ABUNDANCE—Continued

Species	Authorized level A harassment take	Authorized level B harassment take	Total takes as percent of abundance
Antarctic Fur Seal (OW) [b]	134	1,201	0.05
Crabeater Seal (PW)	120	6,129	0.12
Southern Elephant Seal (PW) [b]	94	841	0.23
Leopard Seal (PW) [b]	14	120	0.06
Weddell Seal (PW) [b]	27	240	0.05

[a] Level B harassment takes increased to account for group size assuming one group is encountered during the project
[b] Increased from calculated exposures due to local observational data.

Table 17 also shows authorized takes by harassment for all species as a percentage of stock abundance.

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.

The following mitigation measures are required in the IHA:

- NSF must avoid direct physical interaction with marine mammals during construction activities. If a marine mammal comes within 10 m of such activity, operations must cease and vessels must reduce speed to the minimum level required to maintain steerage and safe working conditions;
- Training must occur between construction supervisors and crews and the PSO team and relevant NSF staff prior to the start of all pile driving and construction activities, and when new personnel join the work, in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures are clearly understood;
- Pile driving activities must be halted upon observation of either a species for which incidental take is not authorized or a species for which incidental take has been authorized but the authorized number of takes has been met, entering or within the Level A or Level B harassment zones as shown in Table 18 and Table 19;
- NSF will establish and implement a shutdown zone of 50 m for fur seals under all pile driving scenarios. The purpose of a shutdown zone is generally to define an area within which shutdown of the activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Shutdown zones typically vary based on the activity type and marine mammal hearing group. Shutdown zones for cetaceans and other pinnipeds are based on Level A harassment isopleths shown in Table 12. Based on observation data, fur seals are known to swim up Hero Inlet (approximately 135 m wide) to haul out. The required 50-m shutdown zone for fur seals can safely be observed, will prevent injury to seals while still allowing seals to move up the inlet where they may haul out on land, and will allow construction to continue safely and efficiently;
- Shutdown zones have been established for all hearing groups under all driving scenarios as shown in Tables 18 and 19. If a marine mammal is observed entering or within the shutdown zones indicated in Tables 18 and 19, pile driving activity must be delayed or halted;
- Monitoring must take place from 30 minutes prior to initiation of pile driving activity through 30 minutes post-completion of pile driving activity. Pre-start clearance monitoring must be conducted during periods of visibility sufficient for the lead PSO to determine the shutdown zones shown in Table 18 and Table 19 are clear of marine mammals. Pile driving may commence following 30 minutes of observation when the determination is made;
- If the shutdown zones shown in Table 18 and Table 19 are not visible due to poor environmental conditions (*e.g.,* excessive wind or fog, high Beaufort state), pile installation would cease until the entirety of the harassment shutdown zones is observable;
- If pile driving is delayed or halted due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily exited and been visually confirmed beyond the shutdown zone or 15 minutes have passed without re-detection of the animal;
- If impact driving should be needed (*i.e.,* for proofing) NSF must use soft start techniques when impact pile driving. Soft start requires contractors to provide an initial set of three strikes at reduced energy, followed by a 30-second waiting period, then two subsequent reduced-energy strike sets. A soft start must be implemented at the start of each day that begins with impact pile driving and at any time impact driving would occur after cessation of

impact pile driving for a period of 30 minutes or longer;

- In-water construction would occur during daylight over a 12-hour workday to minimize the potential for PTS for species that may occur within the Level A harassment zones; and
- When transiting to the site, marine mammal watches must be conducted by crew or those navigating the vessel. When in the Project Area, if a whale is sighted in the path of a support vessel or within 92 m (300 ft) from the vessel, NSF must reduce speed and must not engage the engines until the animals are clear of the area. If a whale is sighted farther than 92 m (300 ft) from the vessel, NSF must maintain a distance of 92 m (300 ft) or greater between the whale and the vessel and reduce speed to 10 knots or less. Vessels must not be operated in such a way as to separate members of a group of whales from other members of the group. A group is defined as being three or more whales observed within a 500 m area and displaying behaviors of directed or coordinated activity (*e.g.,* group feeding).

TABLE 18—SHUTDOWN AND HARASSMENT ZONES (METERS) FOR NON-SIMULTANEOUS PILE INSTALLATION ACTIVITIES

[Level A harassment zone indicated in parentheses where different from shutdown zone]

Pile size, type, and method	Cetaceans			Pinnipeds		Level B harassment zone
	LF	MF	HF	PW	OW	
Dock, 36-in Dia. Pile Installation, 20′ Socket Depth—1 pile/day (DTH)	1,000 (1,981)	70	1,000 (2,253)	1,000 (1,012)	50 (74)	11,659
Dock Abutment, 36-in Dia. Pile Installation, 30′ Socket Depth—1 pile/day (DTH)	1,000 (2,475)	90	1,000 (2,951)	1,000 (1,326)	50 (97)	
RHIB Fender Piles, 24-in Dia. Pile Installation, 20′ Socket—1 pile/day	410	15	485	220	50	
24-in Dia. Template Piles, 10′ Socket Depth—2 piles/day.						
24-in Dia Wave Attenuator Piles, 20′ Socket Depth—1 pile/day.						
Retaining Wall HP Pile inserted in Drilled 24-in Dia Sockets, 20′ Socket Depth—1 pile/day.						
Removal of 24-in Dia. Template Piles—16 piles	55	10	75	35	50	10,000
Removal of Sheet Piles	25	10	35	15	50	4,642
Rock Chipping/Floor Preparation	405	50	720	205	50	123
Anode Installation	10	10	10	10	50	200

TABLE 19—SHUTDOWN AND HARASSMENT ZONES (METERS) FOR SIMULTANEOUS PILE INSTALLATION ACTIVITIES (SHUTDOWN ZONE)

[Level A harassment zone indicated in parentheses where different from shutdown zone]

Daily scenario activity	Cetaceans			Pinnipeds		Level B harassment zone
	LF	MF	HF	PW	OW	
Dock, 36-in Dia. Pile Installation, 20′ Socket Depth—2 pile/day	1,000 (3,002)	110	1,000 (3,576)	1,000 (1,607)	50 (117)	18,478
Dock Abutment, 36-in Dia. Pile Installation, 30′ Socket Depth and 36-in Dia. Pile 20′ Socket Depth	1,000 (3,484)	125	1,000 (4,149)	1,000 (1,864)	50 (136)	
RHIB Fender Piles, 24-in Dia. Pile Installation, 20′ Socket—2 pile/day	650	25	770	350	50	
24-in Dia. Template Piles, 10′ Socket Depth—4 piles/day.						
24-in Dia Wave Attenuator Piles, 20′ Socket Depth—2 pile/day.						
Retaining Wall—HP Pile inserted in Drilled 24-in Dia Sockets, 20′ Socket Depth—2 piles/day.						
Dock, 36-in Dia. Pile Installation, 20′ Socket Depth—1 pile/day and Wave Attenuator, 24-in Dia. Pile Installation, 20′ Socket—1 pile/day	1,000 (2,011)	75	1,000 (2,395)	1,000 (1,076)	50 (78)	
Dock, 36-in Dia. Pile Installation, 20′ Socket Depth—1 pile/day and Wave Attenuator, 24-in Dia. Pile Installation, 20′ Socket—1 pile/day	1,000 (2,885)	105	1,000 (3,436)	1,000 (1,644)	50 (133)	
36-in Dock 20′ socket x 2 Dock Abutment	45	10	65	30	50	34,146
RHIB Fender Piles 24-in x 2	20	10	30	15	50	15,849
24-in template 10′ socket x 4.						
24-in wave attenuator piles—10′socket x 2	35	10	50	20	50	
24-in wave attenuator piles—20′socket x 2.						

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, we have determined that the required mitigation measures provide the means of 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 Project 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 stock;
- 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.

Visual Monitoring

One NMFS-approved, formally trained PSO with prior experience performing the duties of a PSO during construction activities would serve as team leader, supported by three PSOs trained on site or through available online training programs compliant with NMFS standards. PSOs must be independent (*i.e.,* not construction personnel) and have no other assigned tasks during monitoring periods. Prior to initiation of construction, PSOs would complete a training/refresher session on marine mammal monitoring, to be conducted shortly before the anticipated start of the open water season construction activities.

Primary objectives of the training session include:

- Review of the mitigation, monitoring, and reporting requirements provided in the application and IHA, including any modifications specified by NMFS in the authorization;
- Review of marine mammal sighting, identification, and distance estimation methods;
- Review of operation of specialized equipment (bigeye binoculars, GPS); and
- Review of, and classroom practice with, data recording and data entry systems, including procedures for recording data on marine mammal sightings, monitoring operations, environmental conditions, and entry error control.

PSOs must have the following additional qualifications:

- Ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

Two PSOs must be on duty during all in-water construction activities and must record all observations of marine mammals regardless of distance from the pile being driven or covered activity. PSOs shall document any behavioral reactions in concert with distance from piles being driven or removed. PSOs are limited to monitoring no more than 4 hours per shift with sufficient breaks and no more than 12 hours per day to minimize fatigue.

The placement of PSOs during all pile driving activities will ensure that the entire shutdown zones are visible during pile installation. Should environmental conditions deteriorate such that marine mammals within the entire shutdown zone will not be visible (*e.g.,* fog, heavy rain), pile driving activities must be delayed until the PSO is confident marine mammals within the shutdown zone could be detected. The primary monitoring location currently utilized by NSF will be on the roof platform of the Garage Warehouse Recreation (GWR) building (approximately 20 m above sea level) to provide visual coverage of the shutdown zones, as well as the Level A harassment zones to the extent practicable. NMFS agrees that the GWR building is an appropriate monitoring location. The primary PSO can monitor the Project Area generally south-southeast while the second PSO can monitor the area generally west-southwest that may be ensonified. With reticle binoculars the distance potentially visible by a 1.8-m tall PSO from this point would be about 4,360 m. Mounted big eye binoculars would be provided to PSOs for better coverage of the shutdown zones and the Level A harassment zones. NSF believes this location is adequate to monitor the 1,000-m shutdown zone and some of the Level A harassment zone to the extent practicable beyond 1,000 m.

Reporting

A draft marine mammal monitoring report will be submitted to NMFS within 90 days after the completion of pile driving activities, or 60 days prior to a requested date of issuance of any future IHAs for projects at the same location, whichever comes first. The report will include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets. Specifically, the report must include:

- Dates and times (begin and end) of all marine mammal monitoring;
- Construction activities occurring during each daily observation period, including the number and type of piles driven or removed and by what method (*i.e.,* impact or cutting) and the total equipment duration for cutting for each pile or total number of strikes for each pile (impact driving);
- PSO locations during marine mammal monitoring;
- Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance;
- Upon observation of a marine mammal, the following information: Name of PSO who sighted the animal(s) and PSO location and activity at time of sighting; Time of sighting; Identification of the animal(s) (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species; Distance and bearing of each marine mammal observed relative to the pile being driven for each sighting (if pile driving was occurring at time of sighting); Estimated number of animals (min/max/best estimate); Estimated

number of animals by cohort (adults, juveniles, neonates, group composition, etc.); Animal's closest point of approach and estimated time spent within the harassment zone; Description of any marine mammal behavioral observations (*e.g.,* observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (*e.g.,* no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);

- Number of marine mammals detected within each of the Level A harassment and Level B harassment zones, by species; and
- Detailed information about any implementation of any mitigation triggered (*e.g.,* shutdowns and delays), a description of specific actions that ensued, and resulting changes in behavior of the animal(s), if any.

If no comments are received from NMFS within 30 days, the draft final report will constitute the final report. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments.

Reporting Injured or Dead Marine Mammals

In the event that personnel involved in the construction activities discover an injured or dead marine mammal, the IHA-holder must immediately cease the specified activities and report the incident to the Office of Protected Resources (*PR.ITP.MonitoringReports@noaa.gov*), NMFS as soon as feasible. If the death or injury was clearly caused by the specified activity, NSF must immediately cease the specified activities until NMFS is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of the IHA. The IHA-holder must not resume their activities until notified by NMFS. 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.

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).

DTH pile installation, vibratory pile removal, limited impact pile driving for proofing, rock chipping and use of a hydrogrinder have the potential to disturb or displace marine mammals. Specifically, the project activities may result in take, in the form of Level A and Level B harassment from underwater sounds generated from pile driving activities, if individuals are present in the ensonified zone when these activities are underway.

The takes from Level A and Level B harassment would be due to potential PTS, TTS and behavioral disturbance. Even absent mitigation, no mortality or serious injury is anticipated given the nature of the activity and construction method. The potential for harassment would be further minimized through the implementation of the planned mitigation measures (see Mitigation section).

Effects on individual animals 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) (*e.g.,* Thorson and Reyff 2006; Lerma 2014; ABR 2016). Most likely, individuals will simply move away from the sound source and be temporarily displaced from the areas of pile installation, although even this reaction has been observed primarily only in association with impact pile driving. If sound produced by project activities is sufficiently disturbing, animals are likely to simply avoid the area while the activity is occurring. While DTH pile installation associated with the planned project may produce sound at distances of many kilometers from the project site, we expect that animals annoyed by project sound would simply avoid the area and use more-preferred habitats. Furthermore, during any impact driving, implementation of soft start procedures will be required and monitoring of established shutdown zones will be required for all pile installation and removal activities, significantly reducing the possibility of injury. Use of impact driving will be limited to proofing of piles after they have been set in place. Given sufficient notice through use of soft start (for impact driving), marine mammals are expected to move away from an irritating sound source prior to it becoming potentially injurious. This sort of low-level localized displacement, in the absence of any specific known biologically important areas around Palmer Station, would not be expected to impact the reproduction or survival of any individuals.

In addition to the expected effects resulting from authorized Level B harassment, we anticipate that Antarctic minke whales, fin whales, and humpback whales may sustain some limited Level A harassment in the form of auditory injury, given the large PTS zones for LF cetaceans. We are also authorizing take by Level A harassment of Antarctic fur seals, crabeater seals, leopard seals, Weddell seals, and Southern elephant seals since the Level A harassment zones are large relative to the ability to detect these species and they are generally considered more likely than cetaceans to potentially remain within the nearshore Level A harassment zone for longer amounts of time. The Level A harassment zones identified in Table 11 and Table 12 are based upon an animal exposed to impact pile driving multiple piles per day. Considering the short duration to

impact drive or DTH each pile and breaks between pile installations (to reset equipment and move pile into place), this means an animal would have to remain within the area estimated to be ensonified above the Level A harassment threshold for extended periods. This is highly unlikely given typical movement of both cetaceans and pinnipeds throughout the area. However, animals that experience PTS would likely be subjected to slight PTS, *i.e.* minor degradation of hearing capabilities within regions of hearing that align most completely with the frequency range of the energy produced by pile driving, *i.e.,* the low-frequency region below 2 kHz, not severe hearing impairment or impairment in the regions of greatest hearing sensitivity. If hearing impairment occurs, it is most likely that the affected animal would lose a few decibels in its hearing sensitivity, which in most cases is not likely to meaningfully affect its ability to forage and communicate with conspecifics.

The project is also not expected to have significant adverse effects on affected marine mammals' habitats. The project activities would not modify existing marine mammal habitat for a significant amount of time. The activities may increase sedimentation and cause some fish to leave the area of disturbance, thus temporarily impacting marine mammals' foraging opportunities in a limited portion of the foraging range; but, because of the relatively small area of the habitat that may be affected, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences for marine mammals.

The nature of NSF's planned construction activities precludes the likelihood of serious injury or mortality, even absent mitigation. For all species and stocks, take would occur within a limited area (Hero Inlet and nearby waters) that constitutes a small portion of the ranges for authorized species. Level A and Level B harassment will be reduced to the level of least practicable adverse impact through use of mitigation measures described herein. Further, the amount of take authorized is extremely small when compared to stock abundance of authorized species.

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;
- The relatively small number of Level A harassment exposures are anticipated to result only in slight PTS within the lower frequencies associated with pile driving;
- The anticipated incidents of Level B harassment would consist of, at worst, temporary modifications in behavior that would not result in fitness impacts to individuals;
- No adverse effects on affected marine mammals' habitat are anticipated;
- No areas that are known to be specifically important for marine mammal feeding or reproduction have been identified within the Project Area;
- For all species, Hero Inlet and nearby waters represent very small and peripheral part of their ranges; and
- The required mitigation measures (*i.e.,* shutdown zones) are expected to be effective in reducing the effects of the specified activity.

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 specified activity 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. When the predicted number of individuals to be taken is fewer than one third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The amount of take authorized by NMFS is below one third of the estimated stock abundances for all 17 species. For fin whales, the authorized take of individuals is less than 20 percent of the abundance of the affected species or stock, and less than 5 percent for the remainder of the species, as shown in Table 17. This is likely a conservative estimate because it assumes all takes are of different individual animals, which is likely not the case. Some individuals may return multiple times in a day, but PSOs would count them as separate takes if they cannot be individually identified. Based on the analysis contained herein of the specified 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.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 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 whenever we propose to authorize take for endangered or threatened species, in this case with the ESA Interagency Cooperation Division.

There are five marine mammal species (blue whale, fin whale, sei whale, Southern right whale, and sperm whale) with confirmed occurrence in the project area that are listed as endangered under the ESA. The ESA Interagency Cooperation Division issued a Biological Opinion on October 25, 2021, under section 7 of the ESA, on the issuance of an IHA to NSF under section 101(a)(5)(D) of the MMPA by the NMFS Permits and Conservation Division. The BiOp concluded that the specified action is not likely to jeopardize the continued existence of endangered blue whale, fin whale, sei whale, Southern right whale, or sperm whale.

National Environmental Policy Act

NMFS has adopted NSF's Final Initial Environmental Evaluation (IEE), which is generally the equivalent of an environmental assessment (EA) under the Antarctic Conservation Act (16 U.S.C. 2401 *et seq.*). NMFS determined

that the document includes adequate information analyzing the effects on the human environment of issuing the IHA. This IEE was made available to the public for review during the public comment period of the proposed IHA; we did not receive any comments from the public relevant to the IEE. A Finding of No Significant Impact (FONSI) was signed on October 27, 2021. A copy of the IEE and FONSI is available upon online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.*

Authorization

NMFS has issued an IHA to NSF for the potential harassment of small numbers of 17 marine mammal species incidental to pile driving activities associated with construction of the Palmer Station Pier Replacement project at Anvers Island, Antarctica, provided the previously mentioned mitigation, monitoring and reporting requirements are followed.

Dated: November 2, 2021.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–24274 Filed 11–4–21; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB461]

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico

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

ACTION: Notice of issuance of Letter of Authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA), as amended, its implementing regulations, and NMFS' MMPA Regulations for Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico, notification is hereby given that a Letter of Authorization (LOA) has been issued to WesternGeco for the take of marine mammals incidental to the Engagement 2 geophysical survey activity in the Gulf of Mexico.

DATES: The LOA is effective from January 1, 2022, through April 30, 2022.

ADDRESSES: The LOA, LOA request, and supporting documentation are available online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Kim Corcoran, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce 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 authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 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.

Except with respect to certain activities not pertinent here, 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).

On January 19, 2021, we issued a final rule with regulations to govern the unintentional taking of marine mammals incidental to geophysical survey activities conducted by oil and gas industry operators, and those persons authorized to conduct activities on their behalf (collectively ''industry operators''), in Federal waters of the U.S. Gulf of Mexico (GOM) over the course of 5 years (86 FR 5322; January 19, 2021). The rule was based on our findings that the total taking from the specified activities over the 5-year period will have a negligible impact on the affected species or stock(s) of marine mammals and will not have an unmitigable adverse impact on the availability of those species or stocks for subsistence uses. The rule became effective on April 19, 2021.

Our regulations at 50 CFR 217.180 *et seq.* allow for the issuance of LOAs to industry operators for the incidental take of marine mammals during geophysical survey activities and prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat (often referred to as mitigation), as well as requirements pertaining to the monitoring and reporting of such taking. Under 50 CFR 217.186(e), issuance of an LOA shall be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under these regulations and a determination that the amount of take authorized under the LOA is of no more than small numbers.

Summary of Request and Analysis

WesternGeco plans to conduct a long offset sparse 3D ocean bottom node (OBN) survey using airgun arrays as a sound source within the Green Canyon protraction area. Sparse OBN surveys reduce receiver spacing and use dense shots to provide full-azimuth/offset data with uniform sampling in the azimuth/offset (the distance from the source to the receiver) domain (Olofsson *et al.,* 2012). WesternGeco's sound source consists of a 28-element, 5,200 cubic inch (in^3) airgun array. The survey will use two source vessels, each towing three sources at a crossline distance of 100 meters (m) and firing every 8 seconds. Please see WesternGeco's application for additional information.

Consistent with the preamble to the final rule, the survey effort proposed by WesternGeco in its LOA request was used to develop LOA-specific take estimates based on the acoustic exposure modeling results described in the preamble (86 FR 5322, 5398; January 19, 2021). In order to generate the appropriate take number for authorization, the following information was considered: (1) Survey type; (2)

location (by modeling zone [1]); (3) number of days; and (4) season.[2] The acoustic exposure modeling performed in support of the rule provides 24-hour exposure estimates for each species, specific to each modeled survey type in each zone and season.

No 3D OBN surveys were included in the modeled survey types, and use of existing proxies (*i.e.,* 2D, 3D NAZ, 3D WAZ, Coil) is generally conservative for use in evaluation of 3D OBN survey effort, largely due to the greater area covered by the modeled proxies. Summary descriptions of these modeled survey geometries are available in the preamble to the proposed rule (83 FR 29212, 29220; June 22, 2018). Coil was selected as the best available proxy survey type because it most closely resembles sparse OBN, in that both methods use efficient acquisition methodology to acquire Full Azimuth and long offset data to provide better imaging of the sub-surface geological structures. Additionally, the Coil survey pattern was assumed to cover approximately 144 kilometers squared (km^2) per day (compared with approximately 795 km^2, 199 km^2, and 845 km^2 per day for the 2D, 3D NAZ, and 3D WAZ survey patterns, respectively). Among the different parameters of the modeled survey patterns (*e.g.,* area covered, line spacing, number of sources, shot interval, total simulated pulses), NMFS considers area covered per day to be most influential on daily modeled exposures exceeding Level B harassment criteria. Although WesternGeco is not proposing specifically to perform a survey using the coil geometry, its planned 3D OBN survey is expected to cover approximately 62.5 km^2 per day, meaning that the coil proxy is most representative of the effort planned by WesternGeco in terms of predicted Level B harassment exposures.

In addition, all available acoustic exposure modeling results assume use of a 72 element, 8,000 in^3 array. In this case, take numbers authorized through this LOA are considered conservative due to differences in both the airgun array (28 elements, 5,200 in^3) and the daily survey area planned by WesternGeco (62.5 km^2), as compared to those modeled for the rule.

The survey is planned to occur for 48 days in Zone 5. Take estimates for each species, except for sperm whales, are based on the winter season, which produces a greater value for these species. For sperm whales, greater values are produced in the summer season. Since the survey could potentially include up to 30 days in the summer season, sperm whale take estimates were calculated for 30 days in the summer season and 18 days in the winter season. Together, this produces the most conservative take estimate for sperm whales.

For some species, take estimates based solely on the modeling yielded results that are not realistically likely to occur when considered in light of other relevant information available during the rulemaking process regarding marine mammal occurrence in the GOM. Thus, although the modeling conducted for the rule is a natural starting point for estimating take, our rule acknowledged that other information could be considered (see, *e.g.,* 86 FR 5322, 5442 (January 19, 2021), discussing the need to provide flexibility and make efficient use of previous public and agency review of other information and identifying that additional public review is not necessary unless the model or inputs used differ substantively from those that were previously reviewed by NMFS and the public). For this survey, NMFS has other relevant information reviewed during the rulemaking that indicates use of the acoustic exposure modeling to generate a take estimate for certain marine mammal species produces results inconsistent with what is known regarding their occurrence in the GOM. Accordingly, we have adjusted the calculated take estimates for those species as described below.

Rice's whales (formerly known as GOM Bryde's whales) [3] are generally found within a small area in the northeastern GOM in waters between 100–400 m depth along the continental shelf break (Rosel *et al.,* 2016). Whaling records suggest that Rice's whales historically had a broader distribution within similar habitat parameters throughout the GOM (Reeves *et al.,* 2011; Rosel and Wilcox, 2014), and a NOAA survey reported observation of a Rice's whale in the western GOM in 2017 (NMFS, 2018). Habitat-based density modeling identified similar habitat (*i.e.,* approximately 100–400 m water depths along the continental shelf break) as being potential Rice's whale habitat (Roberts *et al.,* 2016), although a ''core habitat area'' defined in the northeastern GOM (outside the scope of the rule) contained approximately 92 percent of the predicted abundance of Rice's whales. See discussion provided at, *e.g.,* 83 FR 29212, 29228, 29280 (June 22, 2018); 86 FR 5322, 5418 (January 19, 2021).

Although it is possible that Rice's whales may occur outside of their core habitat, NMFS expects that any such occurrence would be limited to the narrow band of suitable habitat described above (*i.e.,* 100–400 m). WesternGeco's planned activity will occur in water depths of approximately 600–2,000 m in the central GOM. Thus, NMFS does not expect there to be the reasonable potential for take of Rice's whale in association with this survey and, accordingly, does not authorize take of Rice's whale through this LOA.

Killer whales are the most rarely encountered species in the GOM, typically in deep waters of the central GOM (Roberts *et al.,* 2015; Maze-Foley and Mullin, 2006). The approach used in the acoustic exposure modeling, in which seven modeling zones were defined over the U.S. GOM, necessarily averages fine-scale information about marine mammal distribution over the large area of each modeling zone. NMFS has determined that the approach results in unrealistic projections regarding the likelihood of encountering killer whales.

As discussed in the final rule, the density models produced by Roberts *et al.* (2016) provide the best available scientific information regarding predicted density patterns of cetaceans in the U.S. GOM. The predictions represent the output of models derived from multi-year observations and associated environmental parameters that incorporate corrections for detection bias. However, in the case of killer whales, the model is informed by few data, as indicated by the coefficient of variation associated with the abundance predicted by the model (0.41, the second-highest of any GOM species model; Roberts *et al.,* 2016). The model's authors noted the expected non-uniform distribution of this rarely-encountered species (as discussed above) and expressed that, due to the limited data available to inform the model, it ''should be viewed cautiously'' (Roberts *et al.,* 2015).

NOAA surveys in the GOM from 1992–2009 reported only 16 sightings of killer whales, with an additional 3 encounters during more recent survey effort from 2017–18 (Waring *et al.,* 2013; *www.boem.gov/gommapps*). Two other species were also observed on less than 20 occasions during the 1992–2009 NOAA surveys (Fraser's dolphin and

[1] For purposes of acoustic exposure modeling, the GOM was divided into seven zones. Zone 1 is not included in the geographic scope of the rule.

[2] For purposes of acoustic exposure modeling, seasons include Winter (December–March) and Summer (April–November).

[3] The final rule refers to the GOM Bryde's whale (*Balaenoptera edeni*). These whales were subsequently described as a new species, Rice's whale (*Balaenoptera ricei*) (Rosel *et al.,* 2021).

false killer whale [4]). However, observational data collected by protected species observers (PSOs) on industry geophysical survey vessels from 2002–2015 distinguish the killer whale in terms of rarity. During this period, killer whales were encountered on only 10 occasions, whereas the next most rarely encountered species (Fraser's dolphin) was recorded on 69 occasions (Barkaszi and Kelly, 2019). The false killer whale and pygmy killer whale were the next most rarely encountered species, with 110 records each. The killer whale was the species with the lowest detection frequency during each period over which PSO data were synthesized (2002–2008 and 2009–2015). This information qualitatively informed our rulemaking process, as discussed at 86 FR 5322, 5334 (January 19, 2021), and similarly informs our analysis here.

The rarity of encounter during seismic surveys is not likely to be the product of high bias on the probability of detection. Unlike certain cryptic species with high detection bias, such as *Kogia* spp. or beaked whales, or deep-diving species with high availability bias, such as beaked whales or sperm whales, killer whales are typically available for detection when present and are easily observed. Roberts *et al.* (2015) stated that availability is not a major factor affecting detectability of killer whales from shipboard surveys, as they are not a particularly long-diving species. Baird *et al.* (2005) reported that mean dive durations for 41 fish-eating killer whales for dives greater than or equal to 1 minute in duration was 2.3–2.4 minutes, and Hooker *et al.* (2012) reported that killer whales spent 78 percent of their time at depths between 0–10 m. Similarly, Kvadsheim *et al.* (2012) reported data from a study of four killer whales, noting that the whales performed 20 times as many dives to 1–30 m depth than to deeper waters, with an average depth during those most common dives of approximately 3 m.

In summary, killer whales are the most rarely encountered species in the GOM and typically occur only in particularly deep water. While this information is reflected through the density model informing the acoustic exposure modeling results, there is relatively high uncertainty associated with the model for this species, and the acoustic exposure modeling applies mean distribution data over areas where the species is in fact less likely to occur. NMFS' determination in reflection of the data discussed above, which informed the final rule, is that use of the generic acoustic exposure modeling results for killer whales would result in high estimated take numbers that are inconsistent with the assumptions made in the rule regarding expected killer whale take (86 FR 5322, 5403; January 19, 2021).

In past authorizations, NMFS has often addressed situations involving the low likelihood of encountering a rare species such as killer whales in the GOM through authorization of take of a single group of average size (*i.e.,* representing a single potential encounter). See 83 FR 63268, December 7, 2018. See also 86 FR 29090, May 28, 2021; 85 FR 55645, September 9, 2020. For the reasons expressed above, NMFS determined that a single encounter of killer whales is more likely than the model-generated estimates and has authorized take associated with a single killer whale group encounter (*i.e.,* up to 7 animals).

Based on the results of our analysis, NMFS has determined that the level of taking authorized through the LOA is consistent with the findings made for the total taking allowable under the regulations. See Table 1 in this notice and Table 9 of the rule (86 FR 5322; January 19, 2021).

Small Numbers Determination

Under the GOM rule, NMFS may not authorize incidental take of marine mammals in an LOA if it will exceed ''small numbers.'' In short, when an acceptable estimate of the individual marine mammals taken is available, if the estimated number of individual animals taken is up to, but not greater than, one-third of the best available abundance estimate, NMFS will determine that the numbers of marine mammals taken of a species or stock are small. For more information please see NMFS' discussion of the MMPA's small numbers requirement provided in the final rule (86 FR 5322, 5438; n the January 19, 2021).

The take numbers for authorization are determined as described above in the Summary of Request and Analysis section. Subsequently, the total incidents of harassment for each species are multiplied by scalar ratios to produce a derived product that better reflects the number of individuals likely to be taken within a survey (as compared to the total number of instances of take), accounting for the likelihood that some individual marine mammals may be taken on more than one day (see 86 FR 5322, 5404; January 19, 2021). The output of this scaling, where appropriate, is incorporated into an adjusted total take estimate that is the basis for NMFS' small numbers determination, as depicted in Table 1 for WesternGeco's 48-day survey.

This product is used by NMFS in making the necessary small numbers determination, through comparison with the best available abundance estimates (see discussion at 86 FR 5322, 5391; January 19, 2021). For this comparison, NMFS' approach is to use the maximum theoretical population, determined through review of current stock assessment reports (SAR; *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and model-predicted abundance information (*https://seamap.env.duke.edu/models/Duke/GOM/*). For the latter, for taxa where a density surface model could be produced, we use the maximum mean seasonal (*i.e.,* 3-month) abundance prediction for purposes of comparison as a precautionary smoothing of month-to-month fluctuations and in consideration of a corresponding lack of data in the literature regarding seasonal distribution of marine mammals in the GOM. Information supporting the small numbers determinations is provided in Table 1.

TABLE 1—TAKE ANALYSIS

Species	Authorized take	Scaled take [1]	Abundance [2]	Percent abundance
Rice's whale	0	0	51	0.0
Kogia sp [3]	477	170	4,373	3.9
Beaked whales	5,572	563	3,768	14.9
Bottlenose dolphin	4,540	1,303	176,108	0.7

[4] However, note that these species have been observed over a greater range of water depths in the GOM than have killer whales.

TABLE 1—TAKE ANALYSIS—Continued

Species	Authorized take	Scaled take [1]	Abundance [2]	Percent abundance
Short-finned pilot whale	512	151	1,981	7.6
Sperm whale	1,258	532	2,207	24.1
Atlantic spotted dolphin	1,813	520	74,785	0.7
Clymene dolphin	2,696	774	11,895	6.5
False killer whale	663	196	3,204	6.1
Fraser's dolphin	303	87	1,665	5.2
Killer whale	7	N/A	267	2.6
Melon-headed whale	1,771	523	7,003	7.5
Pantropical spotted dolphin	12,235	3511	102,361	3.4
Pygmy killer whale	417	123	2,126	5.8
Risso's dolphin	792	234	3,764	6.2
Rough-toothed dolphin	958	275	4,853	5.7
Spinner dolphin	3,278	941	25,114	3.7
Striped dolphin	1,053	302	5,229	5.8

[1] Scalar ratios were applied to ''Authorized Take'' values as described at 86 FR 5322, 5404 (January 19, 2021) to derive scaled take numbers shown here.

[2] Best abundance estimate. For most taxa, the best abundance estimate for purposes of comparison with take estimates is considered here to be the model-predicted abundance (Roberts *et al.,* 2016). For those taxa where a density surface model predicting abundance by month was produced, the maximum mean seasonal abundance was used. For those taxa where abundance is not predicted by month, only mean annual abundance is available. For the killer whale, the larger estimated SAR abundance estimate is used.

[3] Includes 25 takes by Level A harassment and 452 takes by Level B harassment. Scalar ratio is applied to takes by Level B harassment only; small numbers determination made on basis of scaled Level B harassment take plus authorized Level A harassment take.

Based on the analysis contained herein of WesternGeco's proposed survey activity described in its LOA application and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the affected species or stock sizes and therefore is of no more than small numbers.

Authorization

NMFS has determined that the level of taking for this LOA request is consistent with the findings made for the total taking allowable under the incidental take regulations and that the amount of take authorized under the LOA is of no more than small numbers. Accordingly, we have issued an LOA to WesternGeco authorizing the take of marine mammals incidental to its geophysical survey activity, as described above.

Dated: November 2, 2021.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–24251 Filed 11–4–21; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB510]

Atlantic Highly Migratory Species; Atlantic Highly Migratory Species Southeast Data, Assessment, and Review Workshops Advisory Panel

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

ACTION: Notice; nominations for shark stock assessment advisory panel.

SUMMARY: NMFS solicits nominations for the Atlantic Highly Migratory Species (HMS) Southeast Data, Assessment, and Review (SEDAR) Workshops Advisory Panel, also known as the ''SEDAR Pool.'' The SEDAR Pool is comprised of a group of individuals who may be selected to consider data and advise NMFS regarding the scientific information, including but not limited to data and models, used in stock assessments for oceanic sharks in the Atlantic Ocean, Gulf of Mexico, and Caribbean Sea. Nominations are being sought for 5-year appointments (2022–2027). Individuals with definable interests in the recreational and commercial fishing and related industries, environmental community, academia, and non-governmental organizations will be considered for membership on the SEDAR Pool.

DATES: Nominations must be received on or before December 6, 2021.

ADDRESSES: You may submit nominations and request the SEDAR Pool Statement of Organization, Practices, and Procedures electronically via email to *SEDAR.pool@noaa.gov.*

Additional information on SEDAR and the SEDAR guidelines can be found at *http://sedarweb.org/.* The terms of reference for the SEDAR Pool, along with a list of current members, can be found at *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/southeast-data-assessment-and-review-and-atlantic-highly.*

FOR FURTHER INFORMATION CONTACT: Karyl Brewster-Geisz, (301) 425–8503.

SUPPLEMENTARY INFORMATION: Atlantic HMS shark fisheries are managed under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*). The 2006 Consolidated Atlantic HMS Fishery Management Plan (2006 Consolidated HMS FMP) and its amendments are implemented by regulations at 50 CFR part 635 under the Magnuson-Stevens Act and the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*).

Background

Section 302(g)(2) of the Magnuson-Stevens Act states that each Council shall establish such advisory panels as are necessary or appropriate to assist it in carrying out its functions under the Act. For the purposes of this section, NMFS applies the above provision to Atlantic HMS management (See section 304(g)(1) of the Magnuson-Stevens Act, which provides that the Secretary will

prepare Fishery Management Plans (FMPs) for HMS and consult with Advisory Panels under section 302(g) for such FMPs). As such, NMFS has established the SEDAR Pool under this section. The SEDAR Pool currently consists of 30 individuals, each of whom may be selected to review data and advise NMFS regarding the scientific information, including but not limited to data and models, used in stock assessments for oceanic sharks in the Atlantic Ocean, Gulf of Mexico, and Caribbean Sea. While the SEDAR Pool was created specifically for Atlantic oceanic sharks, it may be expanded to include other HMS, as needed.

The primary responsibility of individuals in the SEDAR Pool is to review, at SEDAR workshops, the scientific information (including but not limited to data and models) used in stock assessments that are used to advise NMFS about the conservation and management of Atlantic HMS, specifically but not limited to, Atlantic sharks. Individuals in the SEDAR Pool, if selected for a particular workshop, may participate in the various data, assessment, and review workshops during the SEDAR process of any HMS stock assessment. In order to ensure that the review is unbiased, individuals who participated in a data and/or assessment workshop for a particular stock assessment will not be allowed to serve as SEDAR Pool reviewers for the same stock assessment. However, these individuals may be asked to attend the review workshop to answer specific questions from the reviewers concerning the data and/or assessment workshops. Members of the SEDAR Pool may serve as members of other Advisory Panels concurrent with, or following, their service on the SEDAR Pool.

Procedures and Guidelines

A. Participants

The SEDAR Pool is comprised of individuals representing the commercial and recreational fishing communities for Atlantic sharks, the environmental community active in the conservation and management of Atlantic sharks, and the academic community that have relevant expertise either with sharks and/or stock assessment methodologies for marine fish species. In addition, individuals who may not necessarily work directly with sharks, but who are involved in fisheries with similar life history, biology, and fishery issues may be part of the SEDAR Pool. Members of the SEDAR Pool must have demonstrated experience in the fisheries, related industries, research, teaching, writing, conservation, or management of marine organisms. The distribution of representation among the interested parties is not defined or limited.

Additional members of the SEDAR Pool may also include representatives from each of the five Atlantic Regional Fishery Management Councils, each of the 18 Atlantic states, both the U.S. Virgin Islands and Puerto Rico, and each of the relevant interstate commissions: The Atlantic States Marine Fisheries Commission and the Gulf States Marine Fisheries Commission.

If NMFS requires additional members to ensure a diverse pool of individuals for data or assessment workshops, NMFS may request individuals to become members of the SEDAR Pool outside of the annual nomination period.

SEDAR Pool members serve at the discretion of the Secretary. Not all members will attend each SEDAR workshop. Rather, NMFS will invite certain members to participate at specific stock assessment workshops dependent on their ability to participate, discuss, and offer scientific input and advice regarding the species being assessed.

NMFS is not obligated to fulfill any requests (*e.g.,* requests for an assessment of a certain species) that may be made by the SEDAR Pool or its individual members. Members of the SEDAR Pool who are invited to attend stock assessment workshops will not be compensated for their services but may be reimbursed for their travel-related expenses to attend such workshops.

B. Nomination Procedures for Appointments to the SEDAR Pool

Member tenure will be for 5 years. Nominations are sought for terms beginning early in 2022 and expiring in 2027. Nomination packages should include:

1. The name, address, phone number, and email of the applicant or nominee;
2. A description of the applicant's or nominee's interest in Atlantic shark stock assessments or the Atlantic shark fishery;
3. A statement of the applicant's or nominee's background and/or qualifications; and
4. A written commitment that the applicant or nominee shall participate actively and in good faith in the tasks of the SEDAR Pool, as requested.

C. Meeting Schedule

Individual members of the SEDAR Pool meet to participate in stock assessments at the discretion of the Office of Sustainable Fisheries, NMFS. Stock assessment timing, frequency, and relevant species will vary depending on the needs determined by NMFS and SEDAR staff. In 2022 and continuing through 2023, NMFS intends to complete a research track assessment for the hammerhead shark species in the hammerhead shark management group. During an assessment year, meetings and meeting logistics will be determined according to the SEDAR Guidelines. All meetings are open for observation by the public.

Dated: November 2, 2021.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648- XB546]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Falls Bridge Replacement Project in Blue Hill, Maine

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible renewal.

SUMMARY: NMFS has received a request from the Maine Department of Transportation (MEDOT) for authorization to take marine mammals incidental to the Falls Bridge Replacement Project in Blue Hill, Maine. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-year renewal that could be issued under certain circumstances and if all requirements are met, as described in Request for Public Comments at the end of this document. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorizations and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than December 6, 2021.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service and should be sent to *ITP.Meadows@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted online at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Dwayne Meadows, Ph.D., 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.

The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

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 IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs 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 preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

We will review all comments submitted in response to this document prior to concluding our NEPA process or making a final decision on the IHA request.

Summary of Request

On October 7, 2021, NMFS received an application from MEDOT requesting an IHA to take small numbers of seven species (harbor seal (*Phoca vitulina*), gray seal (*Halichoerus grypus*), harp seal (*Pagophilus groenlandicus*), hooded seal (*Cystophora cristata*), harbor porpoise (*Phocoena phocoena*), Atlantic white-sided dolphin (*Lagenorhynchus acutus*) and common dolphin (*Delphinus delphis*)) of marine mammals incidental to pile driving and removal associated with the project. The application was deemed adequate and complete on October 20, 2021. MEDOT's request is for take of a small number of these species by Level B harassment and a small amount of Level A harassment take for harbor seals. Neither MEDOT nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Proposed Activity

Overview

The purpose of the project is to address the structural deficiency of the Falls Bridge and improve public safety. In-water pile driving is needed to create temporary work trestles and support towers and a temporary bridge for vehicle traffic during construction. The work in this application involves the installation of up to 95 24-inch diameter steel piles and then the removal of all piles at the conclusion of the project. The project will take no more than 80 days of in-water pile work.

The pile driving/removal can result in take of marine mammals from sound in the water which may result in behavioral harassment or auditory injury.

Dates and Duration

The IHA is proposed to be effective for one year from July 1, 2022 through June 30, 2023. Exact start dates may change depending on completion of contracting and other environmental compliance, but the IHA will be valid for one year.

Specific Geographic Region

The project is located in the town of Blue Hill, Maine, approximately 28 miles (45 kilometers) southeast of Bangor. The Falls Bridge carries State Route 175 over the Salt Pond Outlet (Figure 1). The Falls Bridge provides the principal opening between the Salt Pond, a one square mile (2.59 square kilometer (km)) tidal estuary, and the Atlantic Ocean. With each tidal cycle a significant volume of water passes through the bridge opening, generating high flow velocities and a ''hydraulic jump'' during mid-tide periods that is colloquially referred to as the reversing falls. The reversing falls, the Falls Bridge itself, and the natural beauty of the area has caused the Falls Bridge to become a destination for sightseers, nature enthusiasts, and recreationists.

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Figure 1-- Map of Proposed Project Area near Blue Hill, Maine.

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The Falls Bridge lies on the transition between an estuarine unconsolidated bottom subtidal system associated with the Salt Pond to the west, and a marine unconsolidated bottom subtidal system associated with Blue Hill Bay to the east. Where the transition occurs, immediately under the bridge and a few hundred feet into Blue Hill Bay, lies a small strip of marine intertidal rocky shore (bedrock dominated). Salinity in the area ranges from 25–35 parts per million, water depth is 0 to 50 feet (0 to 15.2 meters (m)), and water temperature ranges from 38 to 58 degrees Fahrenheit. Ongoing small vessel and recreation/commercial activities (*e.g.,* lobster fishing, sea urchin harvest, sea duck hunting) in Blue Hill Bay likely result in elevated in-air and underwater sound conditions intermittently throughout the year. Background sound levels likely vary seasonally, with the greatest amount of in-air noise associated with the tourism during the summer months, and fishing/hunting activities during late fall and early winter months.

Detailed Description of Specific Activity

The project consists of creating a temporary bridge for vehicle traffic during work on the Falls Bridge; this will require the installation (and then removal when the project is complete) of 15 24-inch steel pipe piles. Work on the main bridge deck is not expected to incidentally harass marine mammals, however in order to facilitate that work, one or two large trestles (up to 100 foot by 125 foot (30.5 by 38 m) long) would be placed in the water next to the bridge. These trestles would require the installation of up to 60 24-inch diameter

steel pipe piles. In addition to the temporary work trestles and temporary bridge, MEDOT anticipates the need for four temporary support towers during the demolition and removal of the existing bridge superstructure. The temporary support towers will be placed at the corners of the tied arch, approximately 20 feet in from the existing bridge abutments. Up to 5 24-inch steel pipe piles will be needed to support each of the temporary support towers, for a total of 20 24-inch steel pipe piles.

In total then the project involves installation and removal of 95 24-inch diameter steel pipe piles. It is expected that all 95 piles will be installed in rock sockets (holes) in the bedrock created by down-the-hole (DTH) equipment. Impact pile driving will be used to seat the piles and potentially drive them through softer substrates. For piles driven in the center of the channel under the bridge (mostly for the trestles), additional lateral stability may require the use of rebar tension anchors drilled deeper into the substrate in the center of the piles and connected to the piles once installed. This would be accomplished by using an 8-inch diameter DTH bit. It is expected that no more than 65 of the 95 piles would require these tension anchors. Once the work on the bridge is complete all 95 piles will be removed using a vibratory hammer.

The DTH and impact hammer installation and vibratory extraction of the piles is expected to take up to 80 days of in-water work. These actions could produce underwater sound at levels that could result in the injury or behavioral harassment of marine mammal species.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting).

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 1 lists all species with expected potential for occurrence in the project area and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2021). 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 2021 U.S. Atlantic Draft SARs (*e.g.,* Hayes *et al.,* 2021).

TABLE 1—SPECIES THAT SPATIALLY CO-OCCUR WITH THE ACTIVITY TO THE DEGREE THAT TAKE IS REASONABLY LIKELY TO OCCUR

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Cetartiodactyla—Cetacea Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae:						
Atlantic white-sided dolphin.	*Lagenorhynchus acutus*	Western North Atlantic	-, -; N	93,233 (0.71, 54,443, See SAR)	544	26
Common dolphin	*Delphinus delphis*	Western North Atlantic	-, -; N	172,8974 (0.21, 145,216, 2016)	1452	399
Family Phocoenidae (porpoises):						
Harbor porpoise	*Phocoena phocoena*	Gulf of Maine/Bay of Fundy	-, -; N	95,543 (0.31; 74,034; 2016)	851	217
Order Carnivora—Superfamily Pinnipedia						
Family Phocidae (earless seals):						
Harbor seal	*Phoca vitulina*	Western North Atlantic	-; N	61,336 (0.08; 57,637, 2018)	1,729	339
Gray seal [4]	*Halichoerus grypus*	Western North Atlantic	-; N	27,300 (0.22, 22,785, 2018)	1,389	4,453
Harp seal	*Pagophilus groenlandicus*	Western North Atlantic	-; N	7,600,000 (UNK, 7,100,000, 2019)	426,000	178,573
Hooded seal	*Cystophora cristata*	Western North Atlantic	-; N	UNK (UNK, UNK, See SAR)	UNK	1,680

[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.* CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance.

[3] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual Mortality/Serious Injury (M/SI) often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

[4] The NMFS stock abundance estimate applies to U.S. population only, however the actual stock abundance is approximately 505,000. The PBR value is estimated for the U.S. population, while the M/SI estimate is provided for the entire gray seal stock (including animals in Canada).

Harbor seal, gray seal, harbor porpoise, Atlantic white-sided dolphin and common dolphin spatially co-occur with the activity to the degree that take is reasonably likely to occur, and we have proposed authorizing take of these species. Harp seal and hooded seal are rare in the project area but could occur and we have proposed authorizing take of these species. All species that could potentially occur in the proposed survey areas are included in the MEDOT's IHA application (see application, Section 3). Humpback whale, North Atlantic right whale, minke whale, sei whale and fin whale could potentially occur in the area. However the spatial and temporal occurrence of these species is very rare, typically further offshore, the species are readily observed, and the applicant would shut down pile driving if they enter the project area (see Proposed Monitoring and Reporting section). Thus take is not expected to occur, and they are not discussed further.

The best available data for marine mammal presence in the vicinity of the project is the result of monitoring surveys completed in preparation for the project. The Shaw Institute (formerly Marine and Environmental Research Institute) was contracted by MEDOT to provide baseline data on seasonal marine mammal observations near the Falls Bridge. Surveys took place on 74 days from June 27, 2017 to July 24, 2018.

Atlantic White-Sided Dolphin

White-sided dolphins occur in temperate and sub-polar waters of the North Atlantic, primarily in continental shelf waters to the 100-m depth contour from central West Greenland to North Carolina (Waring *et al.,* 2019). The Gulf of Maine stock is most common in continental shelf waters from Hudson Canyon to Georges Bank, and in the Gulf of Maine and lower Bay of Fundy. Sighting data indicate seasonal shifts in distribution (Northridge *et al.,* 1997). During January to May, low numbers of white-sided dolphins are found from Georges Bank to Jeffreys Ledge (off New Hampshire), with even lower numbers south of Georges Bank. From June through September, large numbers of white-sided dolphins are found from Georges Bank to the lower Bay of Fundy. From October to December, white-sided dolphins occur at intermediate densities from southern Georges Bank to southern Gulf of Maine (Payne and Heinemann, 1990). This species moves closer inshore in the summers and offshore in the winters.

Common Dolphin

The common dolphin occurs world-wide in temperate to subtropical seas. In the North Atlantic, common dolphins commonly occur over the continental shelf between the 100-m and 2,000-m isobaths and over prominent underwater topography and east to the mid-Atlantic Ridge (Waring *et al.,* 2019). This species is found between Cape Hatteras and Georges Bank from mid-January to May, although they migrate onto the northeast edge of Georges Bank in the fall where large aggregations occur (Kenney and Vigness-Raposa, 2009).

Harbor Porpoise

The harbor porpoise is typically found in colder waters in the northern hemisphere. In the western North Atlantic Ocean, harbor porpoises range from Greenland to as far south as North Carolina (Barco and Swingle, 2014). They are commonly found in bays, estuaries, and harbors less than 200 meters deep (NOAA Fisheries, 2016c). Harbor porpoises in the United States are made up of the Gulf of Maine/Bay of Fundy stock. Gulf of Maine/Bay of Fundy stock are concentrated in the Gulf of Maine in the summer, but are widely dispersed from Maine to New Jersey in the winter. South of New Jersey, harbor porpoises occur at lower densities. Migrations to and from the Gulf of Maine do not follow a defined route (NOAA Fisheries, 2016c).

In most areas, harbor porpoise occur in small groups of just a few individuals. There were 7 harbor porpoise sighted by the Shaw team (Shaw Institute, 2018).

Harbor Seal

The harbor seal occurs in arctic and temperate coastal waters throughout the northern hemisphere, including on both the east and west coasts of the United States. On the east coast, harbor seals can be found from the Canadian Arctic down to Georgia (Blaylock, 1985). Harbor seals occur year-round in Canada and Maine and seasonally (September–May) from southern New England to New Jersey (NOAA Fisheries, 2016d). The range of harbor seals appears to be shifting as they are regularly reported further south than they were historically.

Harbor seals are central-place foragers (Orians and Pearson, 1979) and tend to exhibit strong site fidelity within season and across years, generally forage close to haulout sites, and repeatedly visit specific foraging areas (Suryan and Harvey, 1998; Thompson *et al.,* 1998). Harbor seals tend to forage at night and haul out during the day with a peak in the afternoon between 1 p.m. and 4 p.m. (London *et al.,* 2001).

Harbor seals were the most common marine mammal observed by the Shaw team near Falls Bridge, making up 89 percent of the marine mammals observed (Shaw Institute, 2018).

Gray Seal

The gray seal occurs on both coasts of the Northern Atlantic Ocean and are divided into three major populations (NOAA Fisheries 2016b). The western north Atlantic stock occurs in eastern Canada and the northeastern United States, occasionally as far south as North Carolina. Gray seals inhabit rocky coasts and islands, sandbars, ice shelves and icebergs (NOAA Fisheries 2016b). In the United States, gray seals congregate in the summer to give birth at four established colonies in Massachusetts and Maine (NOAA Fisheries 2016b). From September through May, they disperse and can be abundant as far south as New Jersey. The range of gray seals appears to be shifting as they are regularly being reported further south than they were historically (Rees *et al.* 2016). There was 1 gray seal observed by the Shaw team near the bridge (Shaw Institute 2018).

Harp Seal

The harp seal is a highly migratory species, its range extending throughout the Arctic and North Atlantic Oceans. The world's harp seal population is separated into three stocks, based on associations with specific locations of breeding activities: (1) Off eastern Canada, (2) on the West Ice off eastern Greenland, and (3) in the White Sea off the coast of Russia. The largest stock, which includes two herds that breed either off the coast of Newfoundland/Labrador or near the Magdelan Islands in the Gulf of St. Lawrence, is equivalent to the western North Atlantic stock under the MMPA. The best estimate of abundance for western North Atlantic harp seals, based on the last survey (in 2012) is 7.4 million, with a minimum estimate of 6.9 million (Waring *et al.,* 2020). In U.S. waters, the species has an increasing presence since the 1990s, evidenced by increasing numbers of sightings and strandings in the coastal waters between Maine and New Jersey (Waring *et al.,* 2020). Harp seals that occur in the United States generally occur in New England waters from January through May (Waring *et al.,* 2020).

Hooded Seal

Hooded seals are generally found in deeper waters or on drifting pack ice.

The world population of hooded seals has been divided into three stocks, which coincide with specific breeding areas, as follows: (1) Northwest Atlantic, (2) Greenland Sea, and (3) White Sea (Waring *et al.,* 2020). In the United States, they are considered members of the western North Atlantic stock and generally occur in New England waters from January through May and further south in the summer and fall seasons (Waring *et al.,* 2019).The hooded seal is a highly migratory species, and its range can extend from the Canadian arctic to Puerto Rico. In U.S. waters, the species has an increasing presence in the coastal waters between Maine and Florida (Waring *et al.,* 2019).

Population abundance of hooded seals in the western North Atlantic is derived from pup production estimates, which are developed from whelping pack surveys. The most recent population estimate in the western North Atlantic was derived in 2005. There have been no recent surveys conducted or population estimates developed for this species. The 2005 best population estimate for hooded seals is 593,500 individuals, with a minimum population estimate of 543,549 individuals (Waring *et al.,* 2019). Currently, not enough data are available to determine what percentage of this estimate may represent the population within U.S. waters.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 2.

TABLE 2—MARINE MAMMAL HEARING GROUPS

[NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.,* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. The baleen whales are in the low-frequency hearing group, the dolphins are in the mid-frequency hearing group, harbor porpoises are in the high frequency hearing group, and the seals are in the phocid group.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The Estimated Take section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks.

Acoustic effects on marine mammals during the specified activity can occur from impact and vibratory pile driving and removal and DTH. The effects of underwater noise from MEDOT's proposed activities have the potential to result in Level A or Level B harassment of marine mammals in the action area.

Description of Sound Sources

The marine soundscape is comprised of both ambient and anthropogenic sounds. Ambient sound is defined as the all-encompassing sound in a given place and is usually a composite of sound from many sources both near and far (ANSI 1995). The sound level of an area is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.,* waves, wind, precipitation, earthquakes, ice, atmospheric sound), biological (*e.g.,* sounds produced by marine mammals, fish, and invertebrates), and anthropogenic sound (*e.g.,* vessels, dredging, aircraft, construction).

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise ''ambient'' or ''background'' sound—depends not only on the source levels (as determined by current weather conditions and levels of

biological and shipping activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.,* 1995). The result is that, depending on the source type and its intensity, sound from the specified activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

In-water construction activities associated with the project would include impact and vibratory pile driving and removal and DTH. The sounds produced by these activities fall into one of two general sound types: Impulsive and non-impulsive. Impulsive sounds (*e.g.,* explosions, gunshots, sonic booms, impact pile driving) are typically transient, brief (less than 1 second), broadband, and consist of high peak sound pressure with rapid rise time and rapid decay (ANSI, 1986; NIOSH, 1998; NMFS, 2018). Non-impulsive sounds (*e.g.,* machinery operations such as drilling or dredging, vibratory pile driving, underwater chainsaws, pile clippers, and active sonar systems) can be broadband, narrowband or tonal, brief or prolonged (continuous or intermittent), and typically do not have the high peak sound pressure with raid rise/decay time that impulsive sounds do (ANSI 1995; NIOSH 1998; NMFS 2018). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.,* Ward 1997 in Southall *et al.,* 2007).

Three types of pile hammers would be used on this project: Impact, vibratory, and DTH. Impact hammers operate by repeatedly dropping and/or pushing a heavy piston onto a pile to drive the pile into the substrate. Sound generated by impact hammers is characterized by rapid rise times and high peak levels, a potentially injurious combination (Hastings and Popper, 2005). Vibratory hammers install piles by vibrating them and allowing the weight of the hammer to push them into the sediment. Vibratory hammers produce significantly less sound than impact hammers. Peak Sound pressure Levels (SPLs) may be 180 dB or greater, but are generally 10 to 20 dB lower than SPLs generated during impact pile driving of the same-sized pile (Oestman *et al.,* 2009). Rise time is slower, reducing the probability and severity of injury, and sound energy is distributed over a greater amount of time (Nedwell and Edwards, 2002; Carlson *et al.,* 2005).

A DTH hammer is essentially a drill bit that drills through the bedrock using a rotating function like a normal drill, in concert with a hammering mechanism operated by a pneumatic (or sometimes hydraulic) component integrated into to the DTH hammer to increase speed of progress through the substrate (*i.e.,* it is similar to a ''hammer drill'' hand tool). Rock socketing involves using DTH equipment to create a hole in the bedrock inside which the pile is placed to give it lateral and longitudinal strength. Tension anchoring involves creating a smaller hole inside and deeper than the rock socket. A long piece of rebar is inserted in this hole, grouted or cemented in place, and then the top of the rebar is connected to the top of the pile to increase pile stability. The sounds produced by the DTH method contain both a continuous, non-impulsive component from the drilling action and an intermittent, impulsive component from the hammering effect. Therefore, we treat DTH systems as both intermittent, impulsive (for Level A thresholds) and continuous, non-impulsive (for Level B thresholds) sound source types simultaneously.

The likely or possible impacts of MEDOT's proposed activity on marine mammals could involve both non-acoustic and acoustic stressors. Potential non-acoustic stressors could result from the physical presence of the equipment, vessels, and personnel; however, any impacts to marine mammals are expected to primarily be acoustic in nature. Acoustic stressors include effects of heavy equipment operation during pile installation and removal.

Acoustic Impacts

The introduction of anthropogenic noise into the aquatic environment from pile driving equipment is the primary means by which marine mammals may be harassed from the MEDOT's specified activity. In general, animals exposed to natural or anthropogenic sound may experience physical and psychological effects, ranging in magnitude from none to severe (Southall *et al.,* 2007). Generally, exposure to pile driving and removal and other construction noise has the potential to result in auditory threshold shifts and behavioral reactions (*e.g.,* avoidance, temporary cessation of foraging and vocalizing, changes in dive behavior). Exposure to anthropogenic noise can also lead to non-observable physiological responses such an increase in stress hormones. Additional noise in a marine mammal's habitat can mask acoustic cues used by marine mammals to carry out daily functions such as communication and predator and prey detection. The effects of pile driving and demolition noise on marine mammals are dependent on several factors, including, but not limited to, sound type (*e.g.,* impulsive vs. non-impulsive), the species, age and sex class (*e.g.,* adult male vs. mom with calf), duration of exposure, the distance between the pile and the animal, received levels, behavior at time of exposure, and previous history with exposure (Wartzok *et al.,* 2004; Southall *et al.,* 2007). Here we discuss physical auditory effects (threshold shifts) followed by behavioral effects and potential impacts on habitat.

NMFS defines a noise-induced threshold shift (TS) as a change, usually an increase, in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). The amount of threshold shift is customarily expressed in dB. A TS can be permanent or temporary. As described in NMFS (2018), there are numerous factors to consider when examining the consequence of TS, including, but not limited to, the signal temporal pattern (*e.g.,* impulsive or non-impulsive), likelihood an individual would be exposed for a long enough duration or to a high enough level to induce a TS, the magnitude of the TS, time to recovery (seconds to minutes or hours to days), the frequency range of the exposure (*i.e.,* spectral content), the hearing and vocalization frequency range of the exposed species relative to the signal's frequency spectrum (*i.e.,* how animal uses sound within the frequency band of the signal; *e.g.,* Kastelein *et al.,* 2014), and the overlap between the animal and the source (*e.g.,* spatial, temporal, and spectral).

Permanent Threshold Shift (PTS)—NMFS defines PTS as a permanent, irreversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS 2018). Available data from humans and other terrestrial mammals indicate that a 40 dB threshold shift approximates PTS onset (see Ward *et al.,* 1958, 1959; Ward, 1960; Kryter *et al.,* 1966; Miller, 1974; Ahroon *et al.,* 1996; Henderson and Hu, 2008). PTS levels for marine mammals are

estimates, with the exception of a single study unintentionally inducing PTS in a harbor seal (Kastak *et al.,* 2008), there are no empirical data measuring PTS in marine mammals, largely due to the fact that, for various ethical reasons, experiments involving anthropogenic noise exposure at levels inducing PTS are not typically pursued or authorized (NMFS, 2018).

Temporary Threshold Shift (TTS)—A temporary, reversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). Based on data from cetacean TTS measurements (see Southall *et al.,* 2007), a TTS of 6 dB is considered the minimum threshold shift clearly larger than any day-to-day or session-to-session variation in a subject's normal hearing ability (Schlundt *et al.,* 2000; Finneran *et al.,* 2000, 2002). As described in Finneran (2016), marine mammal studies have shown the amount of TTS increases with cumulative sound exposure level (SEL_{cum}) in an accelerating fashion: At low exposures with lower SEL_{cum}, the amount of TTS is typically small and the growth curves have shallow slopes. At exposures with higher SEL_{cum}, the growth curves become steeper and approach linear relationships with the noise SEL.

Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious (similar to those discussed in auditory masking, below). For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that takes place during a time when the animal is traveling through the open ocean, where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts. We note that reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.,* 2007), so we can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

Currently, TTS data only exist for four species of cetaceans (bottlenose dolphin, beluga whale (*Delphinapterus leucas*), harbor porpoise, and Yangtze finless porpoise (*Neophocoena asiaeorientalis*)) and five species of pinnipeds exposed to a limited number of sound sources (*i.e.,* mostly tones and octave-band noise) in laboratory settings (Finneran, 2015). TTS was not observed in trained spotted (*Phoca largha*) and ringed (*Pusa hispida*) seals exposed to impulsive noise at levels matching previous predictions of TTS onset (Reichmuth *et al.,* 2016). In general, harbor seals and harbor porpoises have a lower TTS onset than other measured pinniped or cetacean species (Finneran, 2015). The potential for TTS from impact pile driving exists. After exposure to playbacks of impact pile driving sounds (rate 2760 strikes/hour) in captivity, mean TTS increased from 0 dB after 15 minute exposure to 5 dB after 360 minute exposure; recovery occurred within 60 minutes (Kastelein *et al.,* 2016). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species. No data are available on noise-induced hearing loss for mysticetes. For summaries of data on TTS in marine mammals or for further discussion of TTS onset thresholds, please see Southall *et al.* (2007), Finneran and Jenkins (2012), Finneran (2015), and Table 5 in NMFS (2018).

Installing piles for this project requires impact pile driving and DTH. There would likely be pauses in activities producing the sound during each day. Given these pauses and that many marine mammals are likely moving through the action area and not remaining for extended periods of time, the potential for TS declines.

Behavioral Harassment—Exposure to noise from pile driving and removal also has the potential to behaviorally disturb marine mammals. Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, l*et al*one the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.,* Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2005).

Disturbance may result in changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where sound sources are located. Pinnipeds may increase their haul out time, possibly to avoid in-water disturbance (Thorson and Reyff, 2006). Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.,* species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.,* Richardson *et al.,* 1995; Wartzok *et al.,* 2004; Southall *et al.,* 2007; Weilgart, 2007; Archer *et al.,* 2010). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.,* 2012), and can vary depending on characteristics associated with the sound source (*e.g.,* whether it is moving or stationary, number of sources, distance from the source). In general, pinnipeds seem more tolerant of, or at least habituate more quickly to, potentially disturbing underwater sound than do cetaceans, and generally seem to be less responsive to exposure to industrial sound than most cetaceans. Please see Appendices B and C of Southall *et al.* (2007) for a review of studies involving marine mammal behavioral responses to sound.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (*e.g.,* bubble nets or sediment plumes), or changes in dive behavior. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (*e.g.,* Croll *et al.,* 2001; Nowacek *et al.,* 2004; Madsen *et al.,* 2006; Yazvenko *et al.,* 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal.

In 2016, the Alaska Department of Transportation and Public Facilities (ADOT&PF) documented observations

of marine mammals during construction activities (*i.e.,* pile driving) at the Kodiak Ferry Dock (see 80 FR 60636, October 7, 2015). In the marine mammal monitoring report for that project (ABR 2016), 1,281 Steller sea lions were observed within the estimated Level B harassment zone during pile driving or drilling (*i.e.,* documented as potential take by Level B harassment). Of these, 19 individuals demonstrated an alert behavior, 7 were fleeing, and 19 swam away from the project site. All other animals (98 percent) were engaged in activities such as milling, foraging, or fighting and did not change their behavior. In addition, two sea lions approached within 20 m of active vibratory pile driving activities. Three harbor seals were observed within the disturbance zone during pile driving activities; none of them displayed disturbance behaviors. Fifteen killer whales and three harbor porpoise were also observed within the Level B harassment zone during pile driving. The killer whales were travelling or milling while all harbor porpoises were travelling. No signs of disturbance were noted for either of these species. Given the similarities in species, activities and habitat, we expect similar behavioral responses of marine mammals to the MEDOT's specified activity. That is, disturbance, if any, is likely to be temporary and localized (*e.g.,* small area movements).

Stress responses—An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.,* Seyle 1950; Moberg 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

Neuroendocrine stress responses often involve the hypothalamus-pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (*e.g.,* Moberg 1987; Blecha 2000). Increases in the circulation of glucocorticoids are also equated with stress (Romano *et al.,* 2004).

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and ''distress'' is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last until the animal replenishes its energetic reserves sufficient to restore normal function.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well-studied through controlled experiments and for both laboratory and free-ranging animals (*e.g.,* Holberton *et al.,* 1996; Hood *et al.,* 1998; Jessop *et al.,* 2003; Krausman *et al.,* 2004; Lankford *et al.,* 2005). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker 2000; Romano *et al.,* 2002b) and, more rarely, studied in wild populations (*e.g.,* Romano *et al.,* 2002a). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as ''distress.'' In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2003), however distress is an unlikely result of this project based on observations of marine mammals during previous, similar projects in the area.

Masking—Sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.,* 1995). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity, and may occur whether the sound is natural (*e.g.,* snapping shrimp, wind, waves, precipitation) or anthropogenic (*e.g.,* pile driving, shipping, sonar, seismic exploration) in origin. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.,* signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.,* sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions. Masking of natural sounds can result when human activities produce high levels of background sound at frequencies important to marine mammals. Conversely, if the background level of underwater sound is high (*e.g.,* on a day with strong wind and high waves), an anthropogenic sound source would not be detectable as far away as would be possible under quieter conditions and would itself be masked. The project area contains active commercial shipping, as well as numerous recreational and other commercial vessel and background sound levels in the area are already elevated.

Airborne Acoustic Effects—Pinnipeds that occur near the project site could be exposed to airborne sounds associated with pile driving and removal that have the potential to cause behavioral harassment, depending on their distance from pile driving activities. Cetaceans are not expected to be exposed to airborne sounds that would result in harassment as defined under the MMPA.

Airborne noise would primarily be an issue for pinnipeds that are swimming or hauled out near the project site within the range of noise levels elevated above the acoustic criteria. There are no known haulouts in the project vicinity. We recognize that pinnipeds in the water could be exposed to airborne sound that may result in behavioral harassment when looking with their heads above water. Most likely, airborne sound would cause behavioral responses similar to those discussed above in relation to underwater sound. For instance, anthropogenic sound could cause hauled out pinnipeds to exhibit changes in their normal behavior, such as reduction in vocalizations, or cause them to temporarily abandon the area and move further from the source. However, these animals would likely previously have been 'taken' because of exposure to underwater sound above the behavioral harassment thresholds, which are generally larger than those associated

with airborne sound. Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further here.

Marine Mammal Habitat Effects

MEDOT's construction activities could have localized, temporary impacts on marine mammal habitat and their prey by increasing in-water sound pressure levels and slightly decreasing water quality. Increased noise levels may affect acoustic habitat (see masking discussion above) and adversely affect marine mammal prey in the vicinity of the project area (see discussion below). During DTH, impact and vibratory pile driving or removal, elevated levels of underwater noise would ensonify the project area where both fishes and mammals occur and could affect foraging success. Additionally, marine mammals may avoid the area during construction, however, displacement due to noise is expected to be temporary and is not expected to result in long-term effects to the individuals or populations. Construction activities are of short duration and would likely have temporary impacts on marine mammal habitat through increases in underwater and airborne sound.

A temporary and localized increase in turbidity near the seafloor would occur in the immediate area surrounding the area where piles are installed or removed. In general, turbidity associated with pile installation is localized to about a 25-foot (7.6-m) radius around the pile (Everitt *et al.,* 1980). The sediments of the project site are sandy and will settle out rapidly when disturbed. Cetaceans are not expected to be close enough to the pile driving areas to experience effects of turbidity, and any pinnipeds could avoid localized areas of turbidity. Local strong currents are anticipated to disburse any additional suspended sediments produced by project activities at moderate to rapid rates depending on tidal stage. Therefore, we expect the impact from increased turbidity levels to be discountable to marine mammals and do not discuss it further.

In-Water Construction Effects on Potential Foraging Habitat

The area likely impacted by the project is relatively small compared to the available habitat. The project area does not include any Biologically Important Areas or other habitat of known importance. The area is highly influenced by anthropogenic activities. The total seafloor area affected by pile installation and removal is a small area compared to the vast foraging area available to marine mammals in the area. At best, the impact area provides marginal foraging habitat for marine mammals and fishes. Furthermore, pile driving and removal at the project site would not obstruct movements or migration of marine mammals.

Avoidance by potential prey (*i.e.,* fish) of the immediate area due to the temporary loss of this foraging habitat is also possible. The duration of fish avoidance of this area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity.

In-water Construction Effects on Potential Prey—Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (*e.g.,* crustaceans, cephalopods, fish, zooplankton). Marine mammal prey varies by species, season, and location. Here, we describe studies regarding the effects of noise on known marine mammal prey.

Fish utilize the soundscape and components of sound in their environment to perform important functions such as foraging, predator avoidance, mating, and spawning (*e.g.,* Zelick and Mann, 1999; Fay, 2009). Depending on their hearing anatomy and peripheral sensory structures, which vary among species, fishes hear sounds using pressure and particle motion sensitivity capabilities and detect the motion of surrounding water (Fay *et al.,* 2008). The potential effects of noise on fishes depends on the overlapping frequency range, distance from the sound source, water depth of exposure, and species-specific hearing sensitivity, anatomy, and physiology. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (pressure-related injuries), and mortality.

Fish react to sounds which are especially strong and/or intermittent low-frequency sounds, and behavioral responses such as flight or avoidance are the most likely effects. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. The reaction of fish to noise depends on the physiological state of the fish, past exposures, motivation (*e.g.,* feeding, spawning, migration), and other environmental factors. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fish; several are based on studies in support of large, multiyear bridge construction projects (*e.g.,* Scholik and Yan, 2001, 2002; Popper and Hastings, 2009). Several studies have demonstrated that impulse sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (*e.g.,* Fewtrell and McCauley, 2012; Pearson *et al.,* 1992; Skalski *et al.,* 1992; Santulli *et al.,* 1999; Paxton *et al.,* 2017). However, some studies have shown no or slight reaction to impulse sounds (*e.g.,* Pena *et al.,* 2013; Wardle *et al.,* 2001; Jorgenson and Gyselman, 2009; Cott *et al.,* 2012).

SPLs of sufficient strength have been known to cause injury to fish and fish mortality. However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells. Halvorsen *et al.* (2012a) showed that a TTS of 4–6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long. Injury caused by barotrauma can range from slight to severe and can cause death, and is most likely for fish with swim bladders. Barotrauma injuries have been documented during controlled exposure to impact pile driving (Halvorsen *et al.,* 2012b; Casper *et al.,* 2013).

The most likely impact to fish from pile driving and removal and construction activities at the project area would be temporary behavioral avoidance of the area. The duration of fish avoidance of this area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated.

Construction activities, in the form of increased turbidity, have the potential to adversely affect forage fish in the project area. Forage fish form a significant prey base for many marine mammal species that occur in the project area. Increased turbidity is expected to occur in the immediate vicinity (on the order of 10 feet (3 m) or less) of construction activities. However, suspended sediments and particulates are expected to dissipate quickly within a single tidal cycle. Given the limited area affected and high tidal dilution rates any effects on forage fish are expected to be minor or negligible.

In summary, given the short daily duration of sound associated with individual pile driving events and the relatively small areas being affected,

pile driving activities associated with the proposed action are not likely to have a permanent, adverse effect on any fish habitat, or populations of fish species. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity. Thus, we conclude that impacts of the specified activity are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species. Further, any impacts to marine mammal habitat are not expected to result in significant or long-term consequences for individual marine mammals, or to contribute to adverse impacts on their populations.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization 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 primarily be by Level B harassment, as use of the acoustic sources has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for Level A harassment to result, primarily for phocids because predicted auditory injury zones are larger than for other groups and harbor seals are common. Auditory injury is unlikely to occur for other species/groups. The proposed mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable. As described previously, no mortality is anticipated or proposed to be authorized for this activity. Below we describe how the take is estimated.

Generally speaking, we estimate take by considering: (1) Acoustic thresholds above which 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). Due to the lack of marine mammal density data available for this location, NMFS relied on local occurrence data and group size to estimate take for some species. Below, we describe the factors considered here in more detail and present the proposed take estimate.

Acoustic Thresholds

NMFS recommends the use of 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 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 120 dB re 1 microPascal (μPa) (root mean square (rms)) for continuous (*e.g.,* vibratory pile-driving) and above 160 dB re 1 μPa (rms) for non-explosive impulsive (*e.g.,* impact pile driving) or intermittent (*e.g.,* scientific sonar) sources.

MEDOT's proposed activity includes the use of continuous (vibratory hammer and DTH) and impulsive (impact pile-driving) sources, and therefore the 120 and 160 dB re 1 μPa (rms) thresholds are 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). MEDOT's activity includes the use of impulsive (impact pile-driving and DTH) and non-impulsive (vibratory hammer and DTH) sources.

These thresholds are provided in Table 3. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2018 Technical Guidance, which may be accessed at *https://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 1µPa²s. 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 sound field in the project area is the existing background noise plus additional construction noise from the proposed project. Marine mammals are expected to be affected via sound generated by the primary components of the project (*i.e.,* impact and vibratory pile driving, and DTH).

In order to calculate distances to the Level A harassment and Level B harassment sound thresholds for the methods and piles being used in this project, NMFS used acoustic monitoring data from other locations to develop source levels for the various pile types, sizes and methods (Table 4).

TABLE 4—PROJECT SOUND SOURCE LEVELS

Method	Estimated noise levels (dB)	Source
DTH—24-inch impulsive (Level A)	154 SELss	Denes *et al.* (2016).
DTH—8-inch impulsive (Level A)	144 SELss	Reyff (2020).
DTH—non-impulsive (Level B) All sizes	166 dB RMS	Denes *et al.* (2016).
Impact—24-inch	203 Pk, 177 SEL	Caltrans (2015).
Vibratory—24-inch	165 RMS	Caltrans (2015).

Note: SEL = single strike sound exposure level; RMS = root mean square.

Level B Harassment Zones

Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater TL is:

TL = B * Log10 (R1/R2),

where

TL = transmission loss in dB
B = transmission loss coefficient; for practical spreading equals 15
R1 = the distance of the modeled SPL from the driven pile, and
R2 = the distance from the driven pile of the initial measurement

The recommended TL coefficient for most nearshore environments is the practical spreading value of 15. This value results in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions, which is the most appropriate assumption for MEDOT's proposed activity in the absence of specific modelling.

MEDOT determined underwater noise would fall below the behavioral effects threshold of 160 dB RMS for impact driving at 1,585 m and the 120 dB rms threshold for vibratory driving at 10,000 m and all diameters of holes created by DTH at 11,660 m (Table 5). It should be noted that based on the bathymetry and geography of the project area, sound will not reach the full distance of the harassment isopleths in all directions (see Application Figures 6–3 and 6–4).

TABLE 5—LEVEL A AND LEVEL B ISOPLETHS (METERS) FOR EACH METHOD

Method	Piles per day	MF	HF	Phocid	Level B
DTH—24-inch	1	6	199	89	11,660
	2	10	315	142	
	3	13	413	186	
DTH—8-inch	1	2	43	20	
	2	2	68	31	
	3	3	89	40	
Impact—24-inch	1	1	35	16	1,585
	2	2	56	25	
	3	3	73	33	
Vibratory—24-inch	3	2	25	11	10,000

Level A Harassment Zones

When the NMFS Technical Guidance (2016) was published, in recognition of the fact that ensonified area/volume could be more technically challenging to predict because of the duration component in the new thresholds, we developed a User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to help predict takes. We note that because of some of the assumptions included in the methods used for these tools, we anticipate that isopleths produced are typically going to be overestimates of some degree, which may result in some degree of overestimate of take by Level A harassment. However, these tools offer the best way to predict appropriate isopleths when more sophisticated 3D modeling methods are not available, and NMFS continues to develop ways to

quantitatively refine these tools, and will qualitatively address the output where appropriate. For stationary sources such as pile driving or removal and DTH using any of the methods discussed above, NMFS User Spreadsheet predicts the closest distance at which, if a marine mammal remained at that distance the whole duration of the activity, it would not incur PTS. We used the User Spreadsheet to determine the Level A harassment isopleths. Inputs used in the User Spreadsheet or models are reported in Table 6 and the resulting isopleths are reported in Table 5 for each of the construction methods and scenarios.

TABLE 6—USER SPREADSHEET INPUTS

Method	Piles per day	Strikes per pile or duration (min)
DTH—24-inch	1–3	54,000
DTH—8-inch	1–3	54,000
Impact—24-inch	1–3	20
Vibratory—24-inch	3	30

Marine Mammal Occurrence and Take Calculation and Estimation

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations. Here we describe how the information provided above is brought together to produce a quantitative take estimate. The main information used to inform take calculations is the Shaw Institute (2018) monitoring study commissioned for this project and discussed above. Density of animals from that study was calculated for either side of the bridge and was applied to the size of the Level B harassment zones (see Application Section 6.3 for full details). A summary of proposed take is in Table 7.

Atlantic White-Sided Dolphin

Density data for this species in the project vicinity do not exist as no Atlantic white-sided dolphin were seen in the Shaw Institute (2018) study. Atlantic white-sided dolphins do not generally occur in the shallow, inland bays and estuaries of Maine. However, some could occur in rare circumstances. To be precautionary, we propose to authorize take for two groups of 20 animals over the course of the project. Therefore, we propose to authorize 40 Level B harassment takes of Atlantic white-sided dolphins. No takes by Level A harassment are expected or proposed for authorization because we expect MEDOT will effectively shutdown for Atlantic white-sided dolphins at the full extent of the very small Level A harassment zones.

Common Dolphin

Density data for this species in the project vicinity do not exist as no common dolphin were seen in the Shaw Institute (2018) study. Common dolphins do not generally occur in the shallow, inland bays and estuaries of Maine. However, some could occur in rare circumstances. As with Atlantic white-sided dolphins above, to be precautionary, we propose to authorize take for two groups of 20 animals over the course of the project. Therefore, we propose to authorize 40 Level B harassment takes of common dolphins. No takes by Level A harassment are expected or proposed for authorization because we expect MEDOT will effectively shutdown for common dolphins at the full extent of the very small Level A harassment zones.

Harbor Porpoise

The peak month of observation from Shaw Institute (2018) was May when the equivalent of 40 harbor porpoise per day would be observed in the Level B harassment zone for DTH. With 80 days of in-water work for the project we estimate potential Level B harassment take events at 3,200 for harbor porpoise. No takes by Level A harassment are expected or proposed for authorization because we expect MEDOT will effectively shutdown for harbor porpoises at the full extent of the small Level A harassment zones.

Harbor Seal

The peak month of observation from Shaw Institute (2018) was August when the equivalent of 99 seals per day would be observed in the Level B harassment zone for DTH. With 80 days of in-water work for the project we estimate potential Level B harassment zone exposures for harbor seals at 7,920.

Because of the larger size of the Level A harassment zones for 24-inch DTH and the abundance of harbor seals, we propose to authorize 2 of the above assumed 99 takes per day by Level A harassment for the 48 days of possible DTH activity. Thus of the 7,920 assumed harbor seal exposures we propose to authorize 96 Level A harassment takes and 7,824 Level B harassment takes.

Gray Seal

The peak month of observation from Shaw Institute (2018) was July when the equivalent of 4 seals per day would be observed in the Level B harassment zone for DTH. With 80 days of in-water work for the project we estimate potential Level B harassment takes for gray seals at 320. No takes by Level A harassment are expected or proposed for authorization because we expect MEDOT will effectively shutdown for gray seals at the full extent of the small Level A harassment zones.

Harp Seal

Density data for this species in the project vicinity do not exist as no harp seals were seen in the Shaw Institute (2018) study. Most sightings on record in Maine occur during the winter months when transient individuals extend their range south in search of food. To be precautionary, we propose to authorize 1 take per month of harp seals. The project has 80 days of in water work equivalent to 16 5-day work weeks or 4 months. Therefore, we propose to authorize 4 Level B harassment takes of harp seals. No takes by Level A harassment are expected or proposed for authorization because we expect MEDOT will effectively shutdown for harp seals at the full extent of the small Level A harassment zones.

Hooded Seal

Density data for this species in the project vicinity also do not exist as no hooded seals were seen in the Shaw Institute (2018) study. Most sightings on record in Maine occur during the winter months when transient individuals extend their range south in search of food. As with harp seals, above, to be precautionary, we propose to authorize 1 take per month of hooded seals. Therefore, we propose to authorize 4 Level B harassment takes of hooded

seals. No takes by Level A harassment are expected or proposed for authorization because we expect MEDOT will effectively shutdown for hooded seals at the full extent of the small Level A harassment zones.

TABLE 7—PROPOSED AUTHORIZED AMOUNT OF TAKING, BY LEVEL A HARASSMENT AND LEVEL B HARASSMENT, BY SPECIES AND STOCK AND PERCENT OF TAKE BY STOCK

Common name	Scientific name	Stock	Level A	Level B	Percent of stock
Harbor porpoise	*Phocoena phocoena*	Gulf Maine/Bay of Fundy	0	3,200	3.3
Atlantic white-sided dolphin	*Lagenorhynchus acutus*	Western North Atlantic	0	40	<0.1
Common dolphin	*Delphinus delphis*	Western North Atlantic	0	40	<0.1
Harbor seal	*Phoca vitulina*	Western North Atlantic	96	7,824	12.8
Gray seal	*Halichoerus grypus*	Western North Atlantic	0	320	<0.1
Harp seal	*Pagophilus groenlandicus*	Western North Atlantic	0	4	<0.1
Hooded seal	*Cystophora cristata*	Western North Atlantic	0	4	NA

NA—not available as there is no official stock size estimate.

Proposed 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.

The following mitigation measures are proposed in the IHA:

- Avoid direct physical interaction with marine mammals during construction activity. If a marine mammal comes within 10 m of such activity, operations must cease and vessels must reduce speed to the minimum level required to maintain steerage and safe working conditions;
- Conduct training between construction supervisors and crews and the marine mammal monitoring team and relevant MEDOT staff prior to the start of all pile driving and DTH activity and when new personnel join the work, so that responsibilities, communication procedures, monitoring protocols, and operational procedures are clearly understood;
- Pile driving activity must be halted upon observation of either a species for which incidental take is not authorized or a species for which incidental take has been authorized but the authorized number of takes has been met, entering or within the harassment zone;
- MEDOT will establish and implement the shutdown zones indicated in Table 8. The purpose of a shutdown zone is generally to define an area within which shutdown of the activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Shutdown zones typically vary based on the activity type and marine mammal hearing group. To simplify implementation of shutdown zones MEDOT has proposed to implement shutdown zones for two groups of marine mammals, cetaceans and pinnipeds, with the shutdown zone in each group being the largest of the shutdown zones for any of the hearing groups contained within that group. MEDOT has also voluntarily proposed to increase shutdown sizes above those we would typically require in order to be precautionary and protective to marine mammals. They have proposed to round-up shutdown zone sizes to the next highest 50 m from the distances in Table 5. For comparison purposes, Table 8 shows both the minimum shutdown zones we would normally require and the shutdown zones MEDOT proposes to implement. NMFS proposes to include the latter in the requested IHA;
- Employ Protected Species Observers (PSOs) and establish monitoring locations as described in the Marine Mammal Monitoring Plan and Section 5 of the IHA. MEDOT must monitor the project area to the maximum extent possible based on the required number of PSOs, required monitoring locations, and environmental conditions. For all DTH, pile driving and removal at least one PSO must be used. The PSO will be stationed as close to the activity as possible;
- The placement of the PSOs during all pile driving and removal and DTH activities will ensure that the entire shutdown zone is visible during pile installation. Should environmental conditions deteriorate such that marine mammals within the entire shutdown zone will not be visible (*e.g.,* fog, heavy rain), pile driving and removal must be delayed until the PSO is confident marine mammals within the shutdown zone could be detected;
- Monitoring must take place from 30 minutes prior to initiation of pile driving activity through 30 minutes post-completion of pile driving activity. Pre-start clearance monitoring must be conducted during periods of visibility sufficient for the lead PSO to determine the shutdown zones clear of marine mammals. Pile driving may commence

following 30 minutes of observation when the determination is made;

• If pile driving is delayed or halted due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily exited and been visually confirmed beyond the shutdown zone or 15 minutes have passed without re-detection of the animal; and

• MEDOT must use soft start techniques when impact pile driving. Soft start requires contractors to provide an initial set of three strikes at reduced energy, followed by a 30-second waiting period, then two subsequent reduced-energy strike sets. A soft start must be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer;

TABLE 8—MINIMUM REQUIRED SHUTDOWN ZONES (METERS) BY HEARING GROUP AND VOLUNTARY PLANNED SHUTDOWN ZONES FOR CETACEANS AND PINNIPEDS FOR EACH METHOD

Method	Piles per day	MF	HF	Phocid	Cetacean	Pinniped
DTH—24-inch	1	10	200	90	200	100
	2	10	320	150	350	200
	3	20	420	190	450	200
DTH—8-inch	1	10	50	20	100	50
	2	10	70	40	100	50
	3	10	90	40	100	50
Impact—24-inch	1	10	40	20	50	50
	2	10	60	30	100	50
	3	10	80	40	100	50
Vibratory—24-inch	3	10	30	20	50	50

Note: First three columns are what NMFS would consider appropriate in this circumstance, and the last two are what the applicant has proposed and what NMFS proposes to include in the IHA.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, NMFS has preliminarily determined that the proposed 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.

Proposed 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 proposed 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.

Visual Monitoring

• Monitoring must be conducted by qualified, NMFS-approved PSOs, in accordance with the following: PSOs must be independent (*i.e.,* not construction personnel) and have no other assigned tasks during monitoring periods. At least one PSO must have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization. Other PSOs may substitute other relevant experience, education (degree in biological science or related field), or training. PSOs must be approved by NMFS prior to beginning any activity subject to this IHA;

• PSOs must record all observations of marine mammals as described in the Section 5 of the IHA and the Marine Mammal Monitoring Plan, regardless of distance from the pile being driven or DTH activity. PSOs shall document any behavioral reactions in concert with distance from piles being driven or removed;

PSOs must have the following additional qualifications:

• Ability to conduct field observations and collect data according to assigned protocols;

• Experience or training in the field identification of marine mammals, including the identification of behaviors;

• Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;

• Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and

• Ability to communicate orally, by radio or in person, with project

personnel to provide real-time information on marine mammals observed in the area as necessary;

- MEDOT must establish the following monitoring locations. For all pile driving and DTH activities, a minimum of one PSO must be assigned to the active pile driving or DTH location to monitor the shutdown zones and as much of the Level A and Level B harassment zones as possible. When a vibratory hammer or DTH is used a second PSO must be located in the Level B harassment zone at one of two shoreline stations east of the bridge (see map in application Figure 13–1).

Reporting

A draft marine mammal monitoring report will be submitted to NMFS within 90 days after the completion of pile driving and removal activities, or 60 days prior to a requested date of issuance of any future IHAs for projects at the same location, whichever comes first. The report will include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets. Specifically, the report must include:

- Dates and times (begin and end) of all marine mammal monitoring;
- Construction activities occurring during each daily observation period, including the number and type of piles driven or removed and by what method (*i.e.,* impact or cutting) and the total equipment duration for cutting for each pile or total number of strikes for each pile (impact driving);
- PSO locations during marine mammal monitoring;
- Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance;
- Upon observation of a marine mammal, the following information: Name of PSO who sighted the animal(s) and PSO location and activity at time of sighting; Time of sighting; Identification of the animal(s) (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species; Distance and bearing of each marine mammal observed relative to the pile being driven for each sighting (if pile driving was occurring at time of sighting); Estimated number of animals (min/max/best estimate); Estimated number of animals by cohort (adults, juveniles, neonates, group composition, etc.); Animal's closest point of approach and estimated time spent within the harassment zone; Description of any marine mammal behavioral observations (*e.g.,* observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (*e.g.,* no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);
- Number of marine mammals detected within the harassment zones, by species; and
- Detailed information about any implementation of any mitigation triggered (*e.g.,* shutdowns and delays), a description of specific actions that ensued, and resulting changes in behavior of the animal(s), if any.

If no comments are received from NMFS within 30 days, the draft final report will constitute the final report. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments.

Reporting Injured or Dead Marine Mammals

In the event that personnel involved in the construction activities discover an injured or dead marine mammal, the IHA-holder must immediately cease the specified activities and report the incident to the Office of Protected Resources (OPR) (*PR.ITP.MonitoringReports@noaa.gov*), NMFS and to Greater Atlantic Regional Stranding Coordinator as soon as feasible. If the death or injury was clearly caused by the specified activity, MEDOT must immediately cease the specified activities until NMFS is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of the IHA. The IHA-holder must not resume their activities until notified by NMFS. 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.

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).

Pile driving and removal and DTH activities have the potential to disturb or displace marine mammals. Specifically, the project activities may result in take, in the form of Level B harassment from underwater sounds generated from pile driving and removal and DTH for all species and a small amount of Level A harassment take for harbor seals. Potential takes could occur if individuals are present in the ensonified zone when these activities are underway.

To avoid repetition, the discussion of our analyses applies to all the species listed in Table 7, given that the anticipated effects of this activity on these different marine mammal stocks are expected to be similar. There is little information about the nature or severity of the impacts, or the size, status, or structure of any of these species or stocks that would lead to a different analysis for this activity.

The takes from Level A and Level B harassment would be due to potential

behavioral disturbance, TTS, and PTS. No serious injury or mortality is anticipated given the nature of the activity and measures designed to minimize the possibility of injury to marine mammals. The potential for harassment is minimized through the construction method and the implementation of the planned mitigation measures (see Proposed Mitigation section).

Many of the Level A harassment zones identified in Table 7 are based upon an animal exposed to pile driving or DTH multiple piles per day. Considering the short duration to impact drive or DTH each pile and breaks between pile installations (to reset equipment and move pile into place), this means an animal would have to remain within the area estimated to be ensonified above the Level A harassment threshold for multiple hours. This is highly unlikely given marine mammal movement throughout the area. If an animal was exposed to accumulated sound energy, the resulting PTS would likely be small (*e.g.,* PTS onset) at lower frequencies where pile driving energy is concentrated, and unlikely to result in impacts to individual fitness, reproduction, or survival.

The nature of the pile driving project precludes the likelihood of serious injury or mortality. For all species and stocks, take would occur within a limited, confined area (adjacent to the Falls Bridge) of the stock's range. Level A and Level B harassment will be reduced to the level of least practicable adverse impact through use of mitigation measures described herein. Further the amount of take proposed to be authorized is small when compared to stock abundance.

Behavioral responses of marine mammals to pile driving at the project site, if any, are expected to be mild and temporary. Marine mammals within the Level B harassment zone may not show any visual cues they are disturbed by activities (as noted during modification to the Kodiak Ferry Dock) or could become alert, avoid the area, leave the area, or display other mild responses that are not observable such as changes in vocalization patterns. Given the short duration of noise-generating activities per day, any harassment would be temporary. There are no other areas or times of known biological importance for any of the affected species.

In addition, it is unlikely that minor noise effects in a small, localized area of habitat would have any effect on the stocks' ability to recover. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, demonstrate that the potential effects of the specified activities will have only minor, short-term effects on individuals. The specified activities are not expected to impact rates of recruitment or survival and will therefore not result in population-level impacts.

In summary and as described above, the following factors primarily support our preliminary 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 is anticipated or authorized;
- Authorized Level A harassment of harbor seals would be very small amounts and of low degree;
- No important habitat areas have been identified within the project area;
- For all species, the project is a very small and peripheral part of their range;
- MEDOT would implement mitigation measures such as soft-starts, and shut downs.

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 proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity 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 section 101(a)(5)(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. When the predicted number of individuals to be taken is fewer than one third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The amount of take NMFS proposes to authorize is below one third of the estimated stock abundance for all species and stocks (in fact, take of individuals is less than 10 percent of the abundance of the affected stocks except for harbor seals where take is 12.8 percent, see Table 7). This is likely a conservative estimate because they assume all takes are of different individual animals which is likely not the case. Some individuals may return multiple times in a day, but PSOs would count them as separate takes if they cannot be individually identified.

In summary and as described above, the following factors primarily support our preliminary determination regarding the incidental take of small numbers of a species or stock:

- The take of marine mammal stocks authorized for take comprises less than 10 percent of any stock abundance (with the exception of harbor seals); and
- Many of the takes would be repeats of the same animal and it is likely that a number of individual animals could be taken 10 or more times.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily 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.

Endangered Species Act

Section 7(a)(2) of the ESA (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 whenever we propose to authorize take for endangered or threatened species.

No incidental take of ESA-listed species is proposed for authorization or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to the MEDOT to conduct the Falls Bridge Replacement Project in

Blue Hill, Maine from July 1, 2022 through June 30, 2023, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.*

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this notice of proposed IHA for the proposed Falls Bridge Replacement Project. We also request at this time comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent Renewal IHA.

On a case-by-case basis, NMFS may issue a one-time 1 year Renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical, or nearly identical, activities as described in the Description of Proposed Activity section of this notice is planned or (2) the activities as described in the Description of Proposed Activity section of this notice would not be completed by the time the IHA expires and a Renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to the needed Renewal IHA effective date (recognizing that Renewal IHA expiration date cannot extend beyond one year from expiration of the initial IHA);
- The request for renewal must include the following:

(1) An explanation that the activities to be conducted under the requested Renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take); and

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized; and

- Upon review of the request for Renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

Dated: November 1, 2021.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–24164 Filed 11–4–21; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed additions and deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete product(s) and service(s) previously furnished by such agencies.

DATES: Comments must be received on or before: December 5, 2021.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following product(s) and service(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
8415–01–575–4031—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, X-Small/Short
8415–01–575–4295—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, X-Small/Regular
8415–01–575–4502—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, X-Small/Long
8415–01–575–4046—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, Small/Short
8415–01–575–4394—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, Small/Regular
8415–01–575–4508—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, Small/Long
8415–01–575–4051—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, Medium/Short
8415–01–575–4445—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, Medium/Regular
8415–01–575–4510—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, Medium/Long
8415–01–575–4246—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, Large/Short
8415–01–575–4427—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, Large/Regular
8415–01–575–4514—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, Large/Long
8415–01–575–4254—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, X-Large/Short
8415–01–575–4457—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, X-Large/Regular
8415–01–575–4515—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, X-Large/Long
8415–01–575–4275—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, XX-Large/Short
8415–01–575–4434—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, XX-Large/Regular
8415–01–575–4518—Jacket, Physical Fitness Uniform, Army, LongS, Universal Camouflage, XX-Large/Long
8415–01–575–4288—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, XXX-Large/Short
8415–01–575–4466—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, XXX-Large/Regular
8415–01–575–4521—Jacket, Physical Fitness Uniform, Army, Long Sleeve, Universal Camouflage, XXX-Large/Long

Designated Source of Supply: Blind Industries & Services of Maryland, Baltimore, MD

Designated Source of Supply: Winston-Salem Industries for the Blind, Inc, Winston-Salem, NC

Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA

NSN(s)—Product Name(s): 7510–01–020–2806—Correction Fluid, Water-Based, Type I, White

Designated Source of Supply: The Lighthouse for the Blind, St. Louis, MO

Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

NSN(s)—Product Name(s):
8415–01–518–4622—Jacket, Physical Training Uniform, USAF, Blue, XXXX-Large/Short
8415–01–518–4623—Jacket, Physical Training Uniform, USAF, Blue, XXXX-Large/Regular

8415–01–518–4647—Jacket, Physical Training Uniform, USAF, Blue, XXXX-Large/Long
Designated Source of Supply: Blind Industries & Services of Maryland, Baltimore, MD
Designated Source of Supply: Winston-Salem Industries for the Blind, Inc, Winston-Salem, NC
Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA

Service(s)

Service Type: Document Management Service
Mandatory for: US Army, Evans Army Community Hospital, Fort Carson, CO, 1650 Cochrane Circle, Fort Carson, CO
Designated Source of Supply: Goodwill Industrial Services Corporation, Colorado Springs, CO
Contracting Activity: DEPT OF THE ARMY, W6QM MICC–FT CARSON

Service Type: Document Destruction Service
Mandatory for: Social Security ODAR, Falls Church, VA (offsite: 9104 Red Branch Road, Columbia, MD), One Skyline Tower, 5107 Leesburg Pike, Falls Church, VA
Contracting Activity: SOCIAL SECURITY ADMINISTRATION, SOCIAL SECURITY ADMINISTRATION

Michael R. Jurkowski,

Acting Director, PL Operations.

[FR Doc. 2021–24255 Filed 11–4–21; 8:45 am]

BILLING CODE 6353–01–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2021–0017]

Notice and Request for Comment Regarding the CFPB's Inquiry Into Big Tech Payment Platforms

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice; request for comment.

SUMMARY: On October 21, 2021, the Consumer Financial Protection Bureau (Bureau or CFPB) ordered six large technology companies operating payments systems in the United States to provide information about certain of their business practices. The information will help the CFPB better understand how these firms use personal payments data and manage data access to users so the Bureau can ensure adequate consumer protection. Accompanying the orders, the Director of the Bureau issued a statement which is reprinted in this document for public review and comment. The Bureau invites any interested parties, including consumers, small businesses, advocates, financial institutions, investors, and experts in privacy, technology, and national security to submit comments to inform the agency's inquiry.

DATES: Comments must be received on or before December 6, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CFPB–2021–0017, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: BigTechPaymentsInquiry@cfpb.gov.* Include Docket No. CFPB–2021–0017 in the subject line of the message.
- *Mail/Hand Delivery/Courier:* Comment Intake—Statement into Big Tech Payment Platforms, Bureau of Consumer Financial Protection, 1700 G Street NW, Washington, DC 20552. Please note that due to circumstances associated with the COVID–19 pandemic, the Bureau discourages the submission of comments by hand delivery, mail, or courier.

Instructions: The Bureau encourages the early submission of comments. All submissions should include document title and docket number. Because paper mail in the Washington, DC area and at the Bureau is subject to delay, commenters are encouraged to submit comments electronically. In general, all comments received will be posted without change to *https://www.regulations.gov.* In addition, once the Bureau's headquarters reopens, comments will be available for public inspection and copying at 1700 G Street NW, Washington, DC 20552, on official business days between the hours of 10 a.m. and 5 p.m. Eastern Time. At that time, you can make an appointment to inspect the documents by telephoning 202–435–7275.

All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Proprietary information or sensitive personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Comments will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Amy Zirkle, Program Manager for Payments & Deposits, (202) 435–7505. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The following statement was issued by the Bureau's Director, Rohit Chopra, on October 21, 2021. This statement accompanied orders issued to six large technology companies operating payments systems in the United States to provide information about certain of their business practices.[1] The Bureau invites any interested parties to submit comments to inform the agency's inquiry.

II. October 21, 2021 Statement

Faster, friction-less, and cheaper payment systems offer significant potential benefits to consumers, workers, their families, and small businesses in the United States. For example, families can send money to friends without delay, or to relatives overseas at lower costs. Fast payment systems can also help small businesses succeed with quicker transactions, lower cost, and more revenue conversion. And faster settlement can reduce the need for families and businesses to borrow.

But payments businesses are network businesses and can gain tremendous scale and market power, potentially posing new risks and undermining fair competition. Furthermore, knowing what we spend our money on is a valuable source of data on consumer behavior. This data can be monetized by companies that seek to profit from behavioral targeting, particularly around advertising and e-commerce. That many Big Tech companies aspire to grow in this space only heightens these concerns.

In China, we can already see the long-term implications of these forces. Alipay and WeChat Pay are deeply imbedded into the lives of the Chinese public, combining messaging, e-commerce and payment functionality into super-apps. In such a market, consumers have little choice but to use these apps and little market power to shape how their data is used.

Today the Consumer Financial Protection Bureau (CFPB) has ordered six technology platforms offering payment services to turn over information about their products, plans and practices when it comes to payments. The orders were issued to Google, Apple, Facebook, Amazon, Square, and PayPal. The CFPB will also study the practices of the Chinese tech giants that offer payments services, such as WeChat Pay and Alipay.

Congress has tasked the CFPB with ensuring that markets for consumer financial products and services are fair, transparent, and competitive. To that end, it has authorized the CFPB to require participants in the marketplace

[1] An example order can be found at *https://www.consumerfinance.gov/documents/10176/cfpb_section-1022_generic-order_2021-10.pdf.*

to provide information that help the Bureau monitor risks to consumers and to publish aggregated findings that are in the public interest.

Little is known publicly about how Big Tech companies will exploit their payments platforms. For example, will the operators engage in invasive financial surveillance and combine the data they collect on consumers with their geolocation and browsing data? [2] Will they in turn use this data to deepen behavioral advertising, engage in price discrimination, or sell to third parties?

Will these companies operate their payment platforms in a manner that interferes with fair, transparent, and competitive markets? Will the payment platforms be truly neutral, or will they use their scale to extract rents from market participants? Will small businesses feel coerced into participating in the payment platform out of fear of being suppressed or hidden in search or product listings? If these tech companies enter a market that competes with other providers on the platform, will these providers be removed or otherwise disadvantaged? What factors will these tech companies use when disqualifying or delisting an individual or business from participating on the platform?

Finally, how will these payment platforms ensure that key consumer protections are adhered to? How effectively do they manage complaints, disputes and errors? Are they sufficiently staffed to ensure adequate steps are taken to address consumer protection and provide responsive customer service when things go wrong? [3]

The CFPB's inquiry will help to inform regulators and policymakers about the future of our payments system. Importantly, it will also yield insights that may help the CFPB to implement other statutory responsibilities, including any potential rulemaking under Section 1033 of the Dodd-Frank Wall Street Reform and Consumer Protection Act. The CFPB's orders build on the efforts of the Federal Trade Commission's work to shed light on the business practices of the largest technology companies in the world.

The CFPB's inquiry is one of many efforts within the Federal Reserve System to plan for the future of real-time payments and to ensure a fair and competitive payments system in our country. The Bureau intends to open a **Federal Register** docket to invite public comment. I invite any interested parties to submit comments to inform the agency's inquiry.

Dated: November 1, 2021.

Rohit Chopra,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2021–24176 Filed 11–4–21; 8:45 am]

BILLING CODE 4810–AM–P

[2] In 2019, I joined global privacy regulators to seek information about Facebook's Libra project. At the time, the company failed to substantively respond. See *https://www.priv.gc.ca/en/opc-news/speeches/2019/s-d_190805/.*

[3] The law currently provides for a number of safeguards in the payments sector, including but not limited to the Electronic Fund Transfer Act, the Gramm-Leach-Bliley Act, and the Consumer Financial Protection Act.

U.S. INTERNATIONAL DEVELOPMENT FINANCE CORPORATION

Notice of Public Hearing

AGENCY: U.S. International Development Finance Corporation

ACTION: Announcement of public hearing.

SUMMARY: The Board of Directors of the U.S. International Development Finance Corporation (''DFC'') will hold a public hearing on December 8, 2021. This hearing will afford an opportunity for any person to present views in accordance with the BUILD Act of 2018. Those wishing to present at the hearing must provide advance notice to the agency as detailed below.

DATES: Public hearing: 2:00 p.m., Wednesday, December 8, 2021.

Deadline for notifying agency of an intent to attend or present at the public hearing: 5:00 p.m., Wednesday, December 1, 2021.

Deadline for submitting a written statement: 5:00 p.m., Wednesday, December 1, 2021.

ADDRESSES: Public hearing: Virtual; Access information provided at the time of attendance registration.

You may send notices of intent to attend, present, or submit a written statement to Catherine F.I. Andrade, DFC Corporate Secretary, via email at *candrade@dfc.gov.*

Instructions: A notice of intent to attend the public hearing or to present at the public hearing must include the individual's name, title, organization, address, email, telephone number, and a concise summary of the subject matter to be presented. Oral presentations may not exceed five (5) minutes. The time for individual presentations may be reduced proportionately, if necessary, to afford all participants who have submitted a timely request an opportunity to be heard. Submission of written statements must include the individual's name, title, organization, address, email, and telephone number. The statement must be typewritten, double-spaced, and may not exceed ten (10) pages.

FOR FURTHER INFORMATION CONTACT: Catherine F.I. Andrade, DFC Corporate Secretary, (202) 336–8768, or *candrade@dfc.gov.*

SUPPLEMENTARY INFORMATION: The public hearing will take place via video- and teleconference. Upon registering, participants and observers will be provided instructions on accessing the hearing. DFC will prepare an agenda for the hearing identifying speakers, setting forth the subject on which each participant will speak, and the time allotted for each presentation. The agenda will be available at the time of the hearing.

Authority: 22 U.S.C. 9613(c).

Catherine F.I. Andrade,

DFC Corporate Secretary.

[FR Doc. 2021–24155 Filed 11–4–21; 8:45 am]

BILLING CODE 3210–02–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Basic Needs for Postsecondary Students Program

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications (NIA) for new awards for fiscal year (FY) 2021 for the Basic Needs for Postsecondary Students Program, Assistance Listing Number 84.116N. This notice relates to the approved information collection under OMB control number 1894–0006.

DATES:

Applications Available: November 5, 2021.

Deadline for Transmittal of Applications: December 6, 2021.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.*

FOR FURTHER INFORMATION CONTACT: Njeri Clark, U.S. Department of Education, 400 Maryland Avenue SW, Room 2B168, Washington, DC 20202–4260. Telephone: (202) 453–6224. Email: *Njeri.Clark@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 Basic Needs for Postsecondary Students Program provides grants to eligible institutions of higher education (IHEs) to support programs that address the basic needs of students and to report on practices that improve outcomes for students.

Background: The Basic Needs for Postsecondary Students Program supports IHEs that demonstrate a commitment to developing or enhancing programs that support the basic needs of students. There is growing evidence that food and housing insecurities compromise the well-being of thousands of undergraduate students across the country, which may reduce the odds that they will complete their degrees or certificates. A recent study of more than 33,000 community college students found that one-third had the lowest levels of food security and could be considered hungry, while just over 50 percent were housing insecure. Fourteen percent of those students surveyed were homeless.[1]

Similarly, the Government Accountability Office analyzed dozens of studies and found rates of food insecurity among college students were typically reported at more than 30 percent.[2] Studies show that if a student has not eaten sufficient nutritious food or slept the night before a class or exam, they will have greater difficulty mastering the material and performing well.[3]

According to the Hope Center for College, Community and Justice's most recent basic needs survey, students of color were more likely to experience basic needs insecurity than their White peers. For students at both two- and four-year institutions, 75 percent of Indigenous students, 70 percent of Black students, and 64 percent of Hispanic or Latino students experienced basic needs insecurity, compared with 54 percent of White students.[4]

Supporting students' basic needs has many benefits for colleges and universities, including boosting academic performance, promoting retention and degree completion, reducing the barriers that returning adults face, and creating bridges between the institution and community organizations.[5] In light of this and the other important issues described above, this competition is designed to promote student success by supporting programs that address the basic needs of students and report on those practices that improve student outcomes. In addition to the absolute priority we have established to address these issues, we are establishing a competitive preference priority to promote comprehensive services to students. This competitive preference priority furthers the goals of the program by supporting projects that meet the needs of the whole student.

Priorities: This notice contains one absolute priority and one competitive preference priority.

We are establishing these priorities for the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1).

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

This priority is:

Strengthening Cross-Agency Coordination and Community Engagement to Advance Systemic Change.

Projects that are designed to take a systemic approach to improving outcomes for underserved students through coordinating efforts with Federal, State, or local agencies, or community-based organizations that support students, to address two or more of the following basic needs:

(1) Food assistance.
(2) Housing.
(3) Transportation.
(4) Health, including access to mental health support.
(5) Childcare.
(6) Dependent care.
(7) Technology.

Competitive Preference Priority: This priority is a competitive preference priority. 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 meets this priority.

This priority is:

Meeting Student Social, Emotional, and Academic Needs. (up to 5 points)

Projects that are designed to support students' social, emotional, and academic needs with a focus on underserved students.

Definitions: We are establishing definitions for ''community college,'' ''Historically Black colleges and universities,'' ''Minority-Serving Institution,'' ''Tribal Colleges or Universities,'' and ''underserved student'' for the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of GEPA. We have defined ''community college'' to ensure that we capture applicable institutions of higher education that offer both associate and bachelor's degrees. We are establishing the definition of ''underserved student'' to target the populations we believe are most in need of the services intended to be provided under this program. The remaining definitions are from 34 CFR 77.1.

Community college means an institution that meets the definition in section 312(f) of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1058(f)); or an IHE (as defined in section 101 of the HEA) that awards degrees and certificates, more than 50 percent of which are not bachelor's degrees (or an equivalent) or master's, professional, or other advanced degrees.

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.

Department means the U.S. Department of Education.

Fiscal year means the Federal fiscal year—a period beginning on October 1 and ending on the following September 30.

Grantee means the legal entity to which a grant is awarded and that is accountable to the Federal Government for the use of the funds provided. The

[1] Goldrick-Rab, S., Broton, K., & Eisenberg, D. (2015). Hungry to Learn: Addressing Food & Housing Insecurity among Undergraduates. Wisconsin HOPE Lab. Retrieved from *http://wihopelab.com/publications/Wisconsin_HOPE_Lab_Hungry_To_Learn.pdf.* Goldrick-Rab, S., Richardson, J., & Hernandez, A. (2017). Hungry and Homeless in College: Results from a National Study of Basic Needs Insecurity in Higher Education. Wisconsin HOPE Lab. Retrieved from *http://wihopelab.com/publications/hungry-and-homeless-in-college-report.pdf*

[2] Government Accountability Office. (2018). Food Insecurity: Better Information Could Help Eligible College Students Access Federal Food Assistance Benefits. Retrieved from *https://www.gao.gov/assets/gao-19-95.pdf.*

[3] Maroto, M.E., Snelling, A., & Linck, H. (2015). Food Insecurity Among Community College Students: Prevalence and Association with Grade Point Average. *Community College Journal of Research and Practice, 39*(6), 515–526. Hershner, S.D., & Chervin, R.D. (2014). Causes and Consequences of Sleepiness Among College Students. *Nature and Science of Sleep, 6,* 73–84.

[4] *hope4college.com/wp-content/uploads/2020/02/2019_RealCollege_Survey_Report.pdf.*

[5] *hope4college.com/wp-content/uploads/2020/02/2019_RealCollege_Survey_Report.pdf.*

grantee is the entire legal entity even if only a particular component of the entity is designated in the grant award notice (GAN). For example, a GAN may name as the grantee one school or campus of a college or university. In this case, the granting agency usually intends, or actually intends, that the named component assume primary or sole responsibility for administering the grant-assisted project or program. Nevertheless, the naming of a component of a legal entity as the grantee in a grant award document shall not be construed as relieving the whole legal entity from accountability to the Federal Government for the use of the funds provided. (This definition is not intended to affect the eligibility provision of grant programs in which eligibility is limited to organizations that may be only components of a legal entity.) The term ''grantee'' does not include any secondary recipients, such as subgrantees and contractors, that may receive funds from a grantee pursuant to a subgrant or contract.

Historically Black colleges and universities means colleges and universities that meet the criteria set out in 34 CFR 608.2.

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.

Note: In developing logic models, applicants may want to use resources such as the Pacific Education Laboratory's Logic Model Application (*www.ies.ed.gov/ncee/edlabs/regions/pacific/elm.asp*).

Minority-Serving Institution means an institution that is eligible to receive assistance under sections 316 through 320 of part A of title III, under part B of title III, or under title V of the HEA.

Performance measure means any quantitative indicator, statistic, or metric used to gauge program or project performance.

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).

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

Tribal Colleges or Universities has the meaning ascribed it in section 316(b)(3) of the HEA.

Underserved student means a student who is enrolled in postsecondary education and is a member of one or more of the following subgroups:

(a) A student who is living in poverty.

(b) A student of color.

(c) A student who is a member of a federally recognized Indian Tribe.

(d) A student with a disability.

(e) A student experiencing homelessness or housing insecurity.

(f) A pregnant, parenting, or caregiving student.

(g) A lesbian, gay, bisexual, transgender, queer, or intersex (LGBTQ+) student.

(h) A student who is the first in their family to attend postsecondary education.

(i) A student enrolling in or seeking to enroll in postsecondary education for the first time at the age of 20 or older.

(j) A student who is enrolled in or is seeking to enroll in postsecondary education who is eligible for a Pell Grant.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed priorities, selection criteria, definitions, and other requirements. Section 437(d)(1) of GEPA, however, allows the Secretary to exempt from rulemaking requirements regulations governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for this program, and therefore qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forgo public comment on the priorities, requirements, and definitions under section 437(d)(1) of GEPA. These priorities, requirements, and definitions will apply to the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition.

Program Authority: 20 U.S.C. 1138–1138d; Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriations Act, 2021, H.R. 7614, 116th Congress (2020); the explanatory statement accompanying H.R. 133 (Pub. L. 116–260).

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in the Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget (OMB) 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.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $4,950,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent fiscal years from the list of unfunded applications from this competition.

Estimated Range of Awards: $750,000 to $990,000 over 36 months.

Estimated Average Size of Award: $865,000.

Maximum Award: We will not make an award exceeding $990,000 for a single budget period of 36 months.

Estimated Number of Awards: 5.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

III. Eligibility Information

1. *Eligible Applicants:* Community Colleges (as defined in this notice) that are Minority-Serving Institutions (as defined in this notice), Historically Black colleges and universities (as defined in this notice), or Tribal Colleges or Universities (as defined in this notice).

Note: The notice announcing the FY 2021 process for designation of eligible institutions, and inviting applications for waiver of eligibility requirements, was published in the **Federal Register** on March 4, 2021 (86 FR 12665). The Department extended the deadline for applications in a notice published in the **Federal Register** on April 13, 2021 (86 FR 19231). Only institutions that the Department determines are eligible, or which are granted a waiver under the process described in the March 4, 2021, notice, and that meet the other eligibility requirements described in this notice, may apply for a grant under this program.

2. a. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* This program limits a grantee's indirect cost reimbursement to eight percent of a modified total direct cost base. We are

establishing this indirect cost limit for the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition in accordance with section 437(d)(1) of GEPA. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

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 the Basic Needs for Postsecondary Students Program, 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).

An applicant may wish to request confidentiality of business information because successful applications may be made available to the public, if requested.

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. However, under 34 CFR 79.8(a), we waive intergovernmental review in order to make awards in a timely manner.

4. *Funding Restrictions:* We reference additional regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 50 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1'' margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger, and 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 applies to the Project Narrative, which is your complete response to the selection criteria, and any response to the competitive preference priorities, if applicable. However, the recommended page limit does not apply to the Application for Federal Assistance form (SF–424); the ED SF–424 Supplement form; the Budget Information—Non-Construction Programs form (ED 524); the assurances and certifications; or the one-page project abstract and supporting budget narrative.

6. *Notice of Intent to Apply:* The Department will be able to review grant applications more efficiently if we know the approximate number of applicants that intend to apply. Therefore, we strongly encourage each potential applicant to notify us of their intent to submit an application. To do so, please email the program contact person listed under **FOR FURTHER INFORMATION CONTACT** with the subject line ''Intent to Apply,'' and include the applicant's name and a contact person's name and email address. Applicants that do not submit a notice of intent to apply may still apply for funding; applicants that do submit a notice of intent to apply are not bound to apply or bound by the information provided.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210. An applicant may earn up to a total of 100 points based on the selection criteria and up to five additional points under the competitive preference priority, for a total score of up to 105 points. The selection criteria are as follows:

a. Need for the project. (Maximum 20 Points)

The Secretary considers the need for the proposed project.

In determining the need for the proposed project, the Secretary considers the following factors:

i. The magnitude of the need for the services to be provided or the activities to be carried out by the proposed project. (Up to 10 points)

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. (Up to 10 points)

b. Quality of the project design. (Maximum 35 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:

i. The extent to which the proposed project will integrate with or build on similar or related efforts to improve relevant outcomes (as defined in this notice), using existing funding streams from other programs or policies supported by community, State, and Federal resources. (Up to 10 points)

ii. The extent to which the proposed project will establish linkages with other appropriate agencies and organizations providing services to the target population. (Up to 10 points)

iii. The extent to which the proposed project demonstrates a rationale (as defined in this notice). (Up to 5 points)

iv. The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs. (Up to 10 points)

c. Quality of project services. (Maximum 25 Points)

The Secretary considers the quality of the services to be provided by the proposed project.

i. In determining the quality of the services to be provided by the proposed

project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (Up to 5 points)

In addition, the Secretary considers the following factors:

ii. The likely impact of the services to be provided by the proposed project on the intended recipients of those services. (Up to 10 points)

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. (Up to 10 points)

d. Quality of the management plan. (Maximum 10 Points)

The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers the adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

e. Quality of the project evaluation. (Maximum 10 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:

i. The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project. (Up to 5 points)

ii. 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. (Up to 5 points)

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).

A panel of two to three non-Federal reviewers will review and score each application in accordance with the selection criteria in this notice, as well as the competitive preference priorities. A rank order funding slate will be made from this review. Awards will be made in rank order according to the average score received from the peer review.

Tiebreaker: If there is more than one application with the same score and insufficient funds to fund all the applications with the same ranking, the first tiebreaker will be to select the applicant with the highest average score under Quality of Project Services. If a second tiebreaker is required, we will select the applicant with the highest average score under Quality of the Project Design. If a third tiebreaker is required, we will select the applicant with the highest average score under Need for the Project. If the tie persists, the application with the highest percentage of students who are Pell grant recipients will be funded.

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this program, the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with:

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a GAN; or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in

the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements, please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case, the Secretary establishes a data collection period.

5. *Performance Measures:* For purposes of evaluating the success of the Basic Needs for Postsecondary Students Program under the Government Performance and Results Act of 1993 and Department reporting under 34 CFR 75.110, the Department will use the following performance measures:

(1) The number of underserved students served by any direct student service supported by the grant.

(2) The annual persistence rate at grantee institutions for all students who are served by any direct student service supported by the grant.

(3) The annual rate of degree or certificate completion at grantee institutions for all students served by any direct student service supported by the grant.

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

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

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

Michelle Asha Cooper,

Acting Assistant Secretary for Postsecondary Education.

[FR Doc. 2021–24362 Filed 11–4–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Modeling and Simulation Program

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2021 for Modeling and Simulation Program (MSP), Assistance Listing Number (ALN) 84.116S. This notice relates to the approved information collection under OMB control number 1894–0006.

DATES:

Applications Available: November 5, 2021.

Deadline for Transmittal of Applications: December 6, 2021.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *https://www.govinfo.gov/content/pkg/Fr-2019-02-13/pdf/2019-02206.pdf.*

FOR FURTHER INFORMATION CONTACT: Robin M. Dabney, U.S. Department of Education, 400 Maryland Avenue SW, Room 2B117, Washington, DC 20202–4260. Telephone: (202) 453–7908. Email: *Robin.Dabney@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 MSP is designed to promote the study of modeling and simulation at institutions of higher education by promoting the enhancement or development of modeling and simulation degree and certificate programs. Additionally, through this program, the Department will create a task force that will include the successful grantees and other content experts to raise awareness and help further define the study of modeling and simulation.

Background: The FY 2021 Consolidated Appropriations Act includes funding for the Modeling and Simulation Program as authorized under section 891 of the Higher Education Act of 1965, as amended (HEA). Modeling and simulation programs utilize simulated interactive models to improve experiential learning in the classroom that represents real-world scenarios. According to the explanatory statement accompanying the FY 2021 Consolidated Appropriations Act, modeling and simulation technology has numerous applications for Federal and State governments and their partners in the defense, education, gaming, shipbuilding, and workforce training sectors, allowing them to

generate data to help make decisions or predictions about their systems.[1] These programs aid in the development of tools or techniques in numerous industries where education and training for high-risk or dangerous situations are not realistic. This program seeks to fund the development or enhancement of degree programs focused on modeling and simulation. Through grant support, we hope to increase the availability and capacity of such programs in today's world.

In addition, the MSP will include the creation of a task force to provide input into the development of curriculum and research on the instructional methods and pedagogy needed to further develop modeling and simulation programs. Applicants funded under this program will be members of the task force, and should include funding requests in their budgets for activities associated with task force membership, in addition to the amount requested for program implementation. In accordance with section 891(b)(1) of the HEA, the activities of the task force will include helping to define the study of modeling and simulation (including the content of modeling and simulation classes and programs); identifying best practices for such study; identifying core knowledge and skills that individuals who participate in modeling and simulation programs should acquire; and providing recommendations to the Secretary. The budget for participation in the task force should be included in the budget narrative and should include travel for at least two to three grantee representatives for two to three in-person meetings and/or site visits to organizations using modeling and simulation technologies to help expand awareness. Budgets should also include costs related to the development of white papers and/or other resources so that grantees can share the knowledge gained through their funded programs, as well as other lessons learned from the task force convenings.

Priorities: This notice contains two absolute priorities. Applicants may only apply under one of the two absolute priorities.

We are establishing these priorities for the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1).

Absolute Priorities: These priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider only applications that meet one of these priorities. Applicants must specify which absolute priority they are responding to in their application abstract.

These priorities are:

Absolute Priority 1—Enhancing Modeling and Simulation at Institutions of Higher Education.

To be considered for a grant under this absolute priority, an eligible institution must include in its application—

(a) A letter from the president or provost of the eligible institution that demonstrates the institution's commitment to the enhancement of the modeling and simulation program at the institution of higher education;

(b) An identification of designated faculty responsible for the enhancement of the institution's modeling and simulation program;

(c) A detailed plan for how the grant funds will be used to enhance a modeling and simulation program that ensures accessibility for students with disabilities;

(d) A listing of line-item costs associated with task force activities, which must include travel for at least two to three annual meetings to be held in Washington, DC and costs associated with a white paper outlining lessons learned from the enhanced modeling and simulation program;

(e) A commitment of a 25 percent cost match for this program. Each eligible institution receiving a grant under this priority must provide, from non-Federal sources, in cash or in-kind, an amount equal to 25 percent of the amount of the grant to carry out the activities supported by the grant; and

(f) Evidence that the institution has an established modeling and simulation degree program, including a major, minor, or career-track program; or has an established modeling and simulation certificate or concentration program.

Absolute Priority 2—Establishing Modeling and Simulation Programs.

To be considered for a grant under this absolute priority, an eligible institution must include in its application—

(a) A letter from the president or provost of the eligible institution that demonstrates the institution's commitment to the establishment of a modeling and simulation program at the institution of higher education;

(b) A detailed plan for how the grant funds will be used to establish a modeling and simulation program that ensures accessibility for students with disabilities;

(c) A description of how the modeling and simulation program established under this priority will complement existing programs and fit into the institution's current program and course offerings;

(d) A listing of line-item costs associated with task force activities, which must include travel for at least two to three annual meetings to be held in Washington, DC, and costs associated with a white paper outlining lessons learned from the established modeling and simulation program; and

(e) A commitment of a 25 percent cost match for this program. Each eligible institution receiving a grant under this subsection must provide, from non-Federal sources, in cash or in-kind, an amount equal to 25 percent of the amount of the grant to carry out the activities supported by the grant.

Definitions: We are establishing the definition of ''modeling and simulation'' for the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of GEPA. This definition expands upon the definition in section 891 of the HEA to provide further clarity consistent with the purpose of the program. The remaining definitions are from 34 CFR 77.1.

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.

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.

Note: In developing logic models, applicants may want to use resources such as the Regional Educational Laboratory Program's (REL Pacific) Education Logic Model Application, available at *https://ies.ed.gov/ncee/edlabs/regions/pacific/elm.asp.*

Other sources include: *https://ies.ed.gov/ncee/edlabs/regions/pacific/pdf/REL_2014025.pdf, https://ies.ed.gov/ncee/edlabs/regions/pacific/pdf/REL_2014007.pdf,* and *https://ies.ed.gov/ncee/edlabs/regions/northeast/pdf/REL_2015057.pdf.*

Modeling and simulation means a field of study that is related to the application of computer science and mathematics to develop a level of understanding of the interaction of the parts of a system and of a system as a

[1] H. Rept. 116–450 (2020).

whole and that uses models (*e.g.,* physical, mathematical, or logical representations of a system, entity, phenomenon, or process) as a basis for simulations to develop data utilized for managerial or technical decision making.

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).

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.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed priorities, selection criteria, definitions, and other requirements. Section 437(d)(1) of GEPA, however, allows the Secretary to exempt from rulemaking requirements regulations governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for this program, and therefore qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forgo public comment on the priorities, definitions, and requirements, under section 437(d)(1) of GEPA.

Program Authority: 20 U.S.C. 1161v; 20 U.S.C. 1138–1138d; Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriations Act, 2021, H.R. 7614, 116th Congress (2020); the explanatory statement accompanying H.R. 133 (Pub. L. 116–260).

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 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.

II. Award Information

Type of Award: Discretionary grant.

Estimated Available Funds: $6,930,000. Approximately fifty percent of available funds will be used to fund an award under Absolute Priority 1, and approximately 50 percent will be used to fund an award under Absolute Priority 2.

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: $750,000 to $1,155,000 for a performance period of 36 months.

Estimated Average Award Size: $866,250.

Maximum Award: $1,155,000 for a performance period of 36 months.

Note: Applicants may include in their award requests up to 10 percent for activities related to task force participation.

Estimated Number of Awards: 8.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

III. Eligibility Information

1. *Eligible Applicants:* A public or private nonprofit institution of higher education, as defined in section 101(a) of the HEA.

2. a. *Cost Sharing or Matching:* In accordance with the requirements in section 891(c)(1)(D) and (d)(1)(D) of the HEA, each eligible institution receiving a grant under this program must provide, from non-Federal sources, in cash or in-kind, an amount equal to 25 percent of the amount of the grant to carry out the activities supported by the grant.

b. *Supplement-Not-Supplant:* This competition involves supplement-not-supplant funding requirements. This program uses the waiver authority of section 437(d)(1) of GEPA to establish this as a supplement-not-supplant program. Grant funds must be used so that they supplement and, to the extent practical, increase the funds that would otherwise be available for the activities to be carried out under this program.

c. *Indirect Cost Rate Information:* For the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of GEPA, a grantee's indirect cost reimbursement is limited to eight percent (8%) of a modified total direct cost base. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

d. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

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 the Modeling and Simulation Program, 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 determing 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 you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review in order to make awards by December 31, 2021.

4. *Funding Restrictions:* A grant awarded under Absolute Priority 1,

Enhancing Modeling and Simulation at IHEs, must be used by an eligible institution to enhance modeling and simulation programs at the institution, which may include—

(a) Expanding the multidisciplinary nature of the institution's modeling and simulation programs;

(b) Recruiting students into the field of modeling and simulation through the provision of fellowships or assistantships;

(c) Creating new courses to complement existing courses and reflect emerging developments in the modeling and simulation field;

(d) Conducting research to support new methodologies and techniques in modeling and simulation; and

(e) Purchasing equipment necessary for modeling and simulation programs.

A grant awarded under Absolute Priority 2, Establishing Modeling and Simulation at IHEs, must be used by an eligible institution to enhance modeling and simulation programs at the institution, which may include—

(a) Establishing, or working toward the establishment of, a modeling and simulation program, including a major, minor, career-track, certificate, or concentration program at the eligible institution;

(b) Providing adequate staffing to ensure the successful establishment of the modeling and simulation program, which may include the assignment of full-time dedicated or supportive faculty; and

(c) Purchasing equipment necessary for modeling and simulation programs.

We reference regulations outlining additional funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 50 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger, and 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. However, the recommended page limit does apply to all of the application narrative Part III.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210. The points assigned to each criterion are indicated in the parentheses next to the criterion. An application may earn up to a total of 100 points based on the selection criteria. All applications will be evaluated based on the selection criteria as follows:

(a) *Significance.* (Maximum 25 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 likely to yield findings that may be utilized by other appropriate agencies and organizations. (up to 5 points)

(ii) The extent to which the proposed project involves the development or demonstration of promising new strategies that build on, or are alternatives to, existing strategies. (up to 10 points)

(iii) 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. (up to 10 points)

(b) *Quality of the project design.* (Maximum 50 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 there is a conceptual framework underlying the proposed research or demonstration activities and the quality of that framework. (up to 10 points)

(ii) The extent to which the proposed activities constitute a coherent, sustained program of training in the field. (up to 10 points)

(iii) The extent to which the proposed project is designed to build capacity and yield results that will extend beyond the period of Federal financial assistance. (up to 10 points)

(iv) The extent to which the proposed project represents an exceptional approach to the priorities established for the competition. (up to 10 points)

(v) The extent to which the proposed project demonstrates a rationale (as defined in this notice). (up to 10 points)

(c) *Quality of project personnel.* (Maximum 5 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. (up to 2 points)

(3) In addition, the Secretary considers the qualifications, including relevant training and experience, of the project director or principal investigator. (up to 3 points)

(d) *Adequacy of resources.* (Maximum 5 points)

(1) The Secretary considers the adequacy of the resources for the proposed project.

(2) In determining the adequacy of resources for the proposed project, the Secretary considers the adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization.

(e) *Quality of the management plan.* (Maximum 5 points)

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(f) *Quality of the project evaluation.* (Maximum 10 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. (up to 5 points)

(ii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes. (up to 5 points)

2. *Review and Selection Process:* We remind potential aplicants 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 CRF 100.4, 104.5, 106.4, 108.8, and 110.23).

A panel of up to three non-Federal reviewers will review and score each application in accordance with the selection criteria. Award(s) will be made in rank order according to the average score received from the peer review for each absolute priority.

Tiebreaker. If there is more than one application with the same score and insufficient funds to fund all the applications with the same ranking, the first tiebreaker will be to select the applicant with the highest average score under the selection criterion Quality of Project Design. If a second tiebreaker is required, we will select the applicant with the highest average score under Adequacy of Resources. If a third tiebreaker is required, we will select the applicant with the highest average score under Significance.

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition, the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgement 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 to Part 200, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII to Part 200, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

5. *Performance Measures:* Under the Government Performance and Results Act of 1993 and for purposes of Department reporting under CFR

75.110, the Department will use the following performance measures to evaluate the success of the MSP:

(a) The number of students enrolled in the established modeling and simulation programs, including major, minor, career-track, certificate, and concentration programs.

(b) The number of new modeling and simulation courses developed under the MSP that reflect emerging developments in the modeling and simulation field.

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format.

The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

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

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

Michelle Asha Cooper,

Acting Assistant Secretary for Postsecondary Education.

[FR Doc. 2021–24360 Filed 11–4–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Rural Postsecondary and Economic Development Grant Program

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2021 for the Rural Postsecondary and Economic Development (RPED) Grant Program, Assistance Listing Number 84.116W. This notice relates to the approved information collection under OMB control number 1894–0006.

DATES:

Applications Available: November 5, 2021.

Deadline for Transmittal of Applications: December 6, 2021.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.*

FOR FURTHER INFORMATION CONTACT: Kurrinn Abrams, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202–4260. Telephone: (202) 453–7906. Email: *kurrinn.abrams2@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 the RPED Grant Program is to improve rates of postsecondary enrollment, persistence, and completion among rural students through development of high-quality career pathways aligned to high-skill, high-wage, and in-demand industry sectors and occupations in the region.

Background: Rural students account for 9.7 million—about 19 percent—of public elementary and secondary school students in the United States and face many challenges accessing postsecondary education.[1] In fact, according to data from the National Education Center for Statistics, 29 percent of individuals from rural areas who are between the ages of 18 and 24 range are enrolled in higher education, compared to almost 48 percent of individuals in that age range who come from cities and 42 percent from suburban areas.[2] For rural students, and particularly low-income rural students, barriers to accessing postsecondary education include difficulties related to accessing high speed internet, transportation, childcare, and healthcare; as well as challenges of experiencing poverty, food insecurity, and housing insecurity. These and other challenges may negatively affect rural students' ability to be academically successful.[3] Many of these challenges exist as a result of geographic isolation, distance from services, and a lack of resources and institutions to support community members. Rural communities are often located in education deserts, which may limit students' exposure or convenient access to postsecondary institutions.[4] Many rural students who do decide to attend college are first-generation students who lack sufficient college preparation in high school,[5] and are unfamiliar with the inner workings of postsecondary institutions, including the college application process and how to finance a college education.[6] These students may feel underprepared for higher education and typically face challenges once in college; many experience hurdles that leave them unable to complete their programs.[7]

Higher education attainment is correlated with greater opportunities for careers, higher individual lifetime earnings, and a better quality of life, and is seen to contribute to the overall well-being of society.[8] Therefore, it is critical to undertake efforts to better prepare students in rural communities for the changing needs of the current workforce, and to create a more skilled workforce that will attract better jobs and provide economic support to the community. However, institutions in rural communities must be given the tools to develop strategies and plans that best serve their population of rural students.[9]

Rural postsecondary institutions are best positioned to enhance and develop programs that improve the preparation, support, and retention of rural students in higher education, and that help them to graduate from college and transition into in-demand and well-paying occupations. To this end, the RPED Grant Program is designed to support postsecondary enrollment and completion by addressing the challenges rural students face accessing postsecondary education that will prepare them for high-skill, high-wage, and in-demand occupations.

[1] *nces.ed.gov/programs/digest/d20/tables/dt20_203.72.asp?current=yes.*

[2] *nces.ed.gov/surveys/ruraled/tables/b.3.b.-1.asp.*

[3] *files.eric.ed.gov/fulltext/EJ1101249.pdf.*

[4] *files.eric.ed.gov/fulltext/EJ1193574.pdf.*

[5] *files.eric.ed.gov/fulltext/EJ1101249.pdf.*

[6] *files.eric.ed.gov/fulltext/EJ1193574.pdf.*

[7] *files.eric.ed.gov/fulltext/EJ1193574.pdf.*

[8] *files.eric.ed.gov/fulltext/EJ1101249.pdf.*

[9] *files.eric.ed.gov/fulltext/EJ1101249.pdf.*

Priorities: This notice contains one absolute priority and two competitive preference priorities.

We are establishing these priorities for the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1).

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

This priority is:

Projects that Increase Postsecondary Access, Affordability, Success, and Completion for Rural Students.

Projects that will serve rural students by—

(a) Increasing the number and proportion of rural students who enroll in and complete postsecondary education programs through activities and strategies related to college preparation, outreach in rural communities, awareness of postsecondary options, recruitment of students from rural communities, support throughout the college application and selection process, and long-term college and career advising relationships with middle and high school students to support them through their transition to postsecondary education;

(b) Supporting the development and implementation of comprehensive student success programs that integrate multiple services or initiatives across academic and student affairs, such as academic advising, structured/guided pathways, career services, student financial aid, transfer support from two- to four-year programs, and other wrap around services;

(c) Supporting the development and implementation of high-quality and accessible learning opportunities for rural students that cater to their unique needs and geographic distance from postsecondary education institutions, and align with career pathways to high-need occupations, including learning opportunities that are accelerated; hybrid online; work-based; or flexible for working students;

(d) Supporting the development or implementation of evidence-based strategies to promote rural students' development of the knowledge and skills necessary for success in the workforce and in high-need occupations, including career training that leads to good jobs in fields relevant to the regional economy, and to raise awareness of, and access to, paid internship, fellowship, apprenticeship, and job opportunities; and

(e) Implementing a sustainability plan to maintain programs and services after completion of the grant.

Competitive Preference Priorities: These priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i), we award up to an additional 10 points to an application, depending on how well the application meets these priorities. An applicant may address one or both of the competitive preference priorities. The point value for each priority is in parenthesis.

These priorities are:

Competitive Preference Priority 1—Supporting Access to Technology (Up to 5 points).

Projects that are designed to promote educational equity and adequacy in resources and opportunity for rural students through student-centered learning models that provide access to technology and leverage technology to address learner variability (*e.g.,* universal design for learning, competency-based education, project-based learning, or hybrid/blended learning) and provide high-quality learning content, applications, or tools.

Competitive Preference Priority 2—Strengthening Cross-Agency Coordination and Community Engagement to Advance Systemic Change (Up to 5 points).

Projects that are designed to take a systemic approach to improving outcomes for rural students through the development of career pathways aligned to high-skill, high-wage or in-demand industry sectors and occupations in the region in partnership with regional economic development entities, workforce agencies, regional employers, or other relevant nonprofit organizations.

Definitions: We are establishing the definitions of ''competency-based education'', ''regional economic development entity'', and ''rural area'' for the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of GEPA. The definitions of ''demonstrates a rationale'', ''evidence-based'', ''logic model'', ''project component'', and ''relevant outcome'' are from 34 CFR 77.1. The definition of ''universal design for learning'' is from section 101 of the Higher Education Act of 1965, as amended (HEA).

Competency-based education (also called proficiency-based or mastery-based learning) means learning based on knowledge and skills that are transparent and measurable. Progression is based on demonstrated mastery of what students are expected to know (knowledge) and be able to do (skills).

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 the proposed project component is supported by evidence that demonstrates a rationale.

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.

Note: In developing logic models, applicants may want to use resources such as the Regional Educational Laboratory Program's (REL Pacific) Education Logic Model Application, available at *https://ies.ed.gov/ncee/edlabs/regions/pacific/elm.asp.* Other sources include: *https://ies.ed.gov/ncee/edlabs/regions/pacific/pdf/REL_2014025.pdf, https://ies.ed.gov/ncee/edlabs/regions/pacific/pdf/REL_2014007.pdf,* and *https://ies.ed.gov/ncee/edlabs/regions/northeast/pdf/REL_2015057.pdf.*

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).

Regional economic development entity means an entity working to promote economic development in, or employing residents of, a rural area, which may include local boards (as defined in section 3(33) of the Workforce Innovation and Opportunity Act), Chambers of Commerce, and employers in the rural region covered by the grant.

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 area means an area that is characterized by locale code 41, 42, or 43. Please refer to the NCES locale lookup map: *https://nces.ed.gov/programs/maped/LocaleLookup/.*

Universal design for learning means a scientifically valid framework for guiding educational practice that—(a) provides flexibility in the ways information is presented, in the ways students respond or demonstrate

knowledge and skills, and in the ways students are engaged; and (b) reduces barriers in instruction, provides appropriate accommodations, supports, and challenges, and maintains high achievement expectations for all students, including students with disabilities and students who are limited English proficient.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed priorities, selection criteria, definitions, and other requirements. Section 437(d)(1) of GEPA, however, allows the Secretary to exempt from rulemaking requirements regulations governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for this program, and therefore qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forgo public comment on the priorities, requirements, and definitions under section 437(d)(1) of GEPA.

Program Authority: 20 U.S.C. 1138–1138d; Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriations Act, 2021, H.R. 7614, 116th Congress (2020); the explanatory statement accompanying H.R. 133 (Pub. L. 116–260).

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 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.

II. Award Information

Type of Award: Discretionary grant.

Estimated Available Funds: $9,900,000.

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: $1,100,000 to $1,237,500.

Estimated Average Size of Awards: $1,200,000.

Maximum Award: $1,237,500.

Note: The maximum award is based on a 3-year budget period. Applicants will need to prepare a multiyear budget request for up to 3 years.

Estimated Number of Awards: 8.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

III. Eligibility Information

1. *Eligible Applicants:* For the FY 2021 grant competition in accordance with section 437(d)(1) of GEPA, the following are eligible applicants: Public and private nonprofit institutions of higher education (IHEs), as defined in section 101 of the HEA, with enrollment of at least 30 percent of students who attended high schools located in rural areas (as defined in this notice).

2. a. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

b. *Supplement-Not-Supplant:* For the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, this competition involves supplement-not-supplant funding requirements. This program uses the waiver authority of section 437(d)(1) of GEPA to establish this as a supplement-not-supplant program. Grant funds must be used so that they supplement and, to the extent practical, increase the funds that would otherwise be available for the activities to be carried out under the grant and in no case supplant those funds.

c. *Indirect Cost Rate Information:* For the FY 2021 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of GEPA, a grantee's indirect cost reimbursement is limited to eight percent (8%) of a modified total direct cost base. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

d. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

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 program 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 December 31, 2021.

3. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 50 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, except 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 the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract. However, the recommended page limit does apply to all of the application narrative.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from 34 CFR 75.210. Applicants should address each of the selection criteria. 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 and up to 10 additional points

under the competitive preference priorities, for a total score of up to 110 points. All applications will be evaluated based on the selection criteria as follows:

(a) *Quality of the project design.* (Maximum 35 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. (Up to 10 points)

(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. (Up to 10 points)

(iii) The extent to which the design of the proposed project includes a thorough, high-quality review of the relevant literature, a high-quality plan for project implementation, and the use of appropriate methodological tools to ensure successful achievement of project objectives. (Up to 5 points)

(iv) The extent to which the proposed project demonstrates a rationale (as defined in this notice). (Up to 5 points)

(v) The extent to which the proposed project is designed to build capacity and yield results that will extend beyond the period of Federal financial assistance. (Up to 3 points)

(vi) 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. (Up to 2 points)

(b) *Quality of the management plan.* (Maximum 35 points)

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan, the Secretary considers the following factors:

(i) 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. (Up to 10 points)

(ii) The extent to which the costs are reasonable in relation to the number of persons to be served and to the anticipated results and benefits. (Up to 5 points)

(iii) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project. (Up to 5 points)

(iv) The adequacy of procedures for ensuring feedback and continuous improvement in the operation of the proposed project. (Up to 5 points)

(v) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project. (Up to 10 points)

(c) *Adequacy of resources.* (Maximum 10 points)

(1) The Secretary considers the adequacy of resources for the proposed project.

(2) In determining the adequacy of resources for the proposed project, the Secretary considers the following factors:

(i) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization. (Up to 5 points)

(ii) The relevance and demonstrated commitment of each partner in the proposed project to the implementation and success of the project. (Up to 5 points)

(d) *Quality of the project evaluation.* (Maximum 20 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:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project. (Up to 10 points)

(ii) The extent to which the methods of evaluation provide for examining the effectiveness of project implementation strategies. (Up to 10 points)

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 also 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).

A panel of two non-Federal reviewers will review and score each application in accordance with the selection criteria and the competitive preference priorities. Award(s) will be made in rank order according to the average score received from the peer review.

Tiebreaker. In the event there are two or more applications with the same final score, and there are insufficient funds to fully support each of these applications, the Department will use other information to select applications (34 CFR 75.217). The Department will apply the following procedure to determine which application or applications will receive an award:

First Tiebreaker: The first tiebreaker will be the highest average score for the selection criterion ''Quality of the Project Design.'' If a tie remains, the second tiebreaker will be utilized.

Second Tiebreaker: The second tiebreaker will be the highest average score for the selection criterion ''Quality of the Management Plan.'' If a tie remains, the third tiebreaker will be utilized.

Third Tiebreaker: The third tiebreaker will be the highest average score for the selection criterion ''Quality of the Project Evaluation.''

Fourth Tiebreaker: The fourth tiebreaker will be the highest percentage of students who attended high schools in rural areas.

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition, the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.205(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.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

5. *Performance Measures:* Under the Government Performance and Results Act of 1993 and for purposes of Department reporting under 34 CFR 75.110, the Department will use the following performance measures to evaluate the success of the RPED Grants Program.

1. The number of rural students served by direct student services supported by the grant.

2. The change in the annual enrollment rate at grantee institutions of rural students who are served by direct student services supported by the grant from one year to the next.

3. The number of rural students served by direct student services supported by the grant that transfer to a four-year institution or obtain a degree or certificate of completion.

4. The number of rural students served by the program who obtain a paid internship, apprenticeship, or employment.

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

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

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

Michelle Asha Cooper,

Acting Assistant Secretary for Postsecondary Education.

[FR Doc. 2021–24361 Filed 11–4–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–426–A]

Application To Export Electric Energy; Rassini Energy Project, LLC

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: Rassini Energy Project, LLC (Applicant or REP) has applied for authorization to transmit electric energy from the United States to Mexico pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before December 6, 2021.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to (202) 586–8008.

FOR FURTHER INFORMATION CONTACT: Matt Aronoff, (202) 586–5863, *matthew.aronoff@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electricity from the United States to a foreign country, pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 42 U.S.C. 7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)).

On October 22, 2021, REP filed an application with DOE (Application or App.) to renew its existing authorization to transmit electric energy from the United States to Mexico. *See* App. at 1. REP states that it ''is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business located [in] Plymouth, Michigan.'' *Id.* REP adds that it is a ''subsidiary of Rassini International Investments, L.L.C., a Delaware limited liability company (Rassini).'' *Id.* REP represents that, ''[n]either [it] nor any of its affiliates owns, controls, or operates any electric generation, electric distribution or transmission facilities, or natural gas distribution or transmission facilities, . . . or generation sites in the United States.'' *Id.* at 2. REP also states that, ''neither [it] nor any of its affiliates has a franchise or service territory for the sale, distribution or transmission or electricity or natural gas in the United States.'' *Id.* at 2.

REP contends that its proposed exports ''would not negatively impact electric supply, nor would they impair the coordination of the electric grid under the DOE's standards.'' App. at 4. REP represents that ''the export limits imposed by the Department on the international transmission facilities are sufficient to ensure that exports by Applicant would not impede or tend to impede the coordinated use of transmission facilities within the meaning of FPA Section 202(e).'' *Id.* at 6.

The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning REP's application to export electric energy to Mexico should be clearly marked with OE Docket No. EA–426–A. Additional copies are to be provided directly to Juan Pablo Rosas P., Pedregal 24—Piso 7, Col. Molino del Rey C.P., 11040, Ciudad de México, Mexico, *jprosas@rassini.com;* William D. DeGrandis, 2050 M Street NW, Washington, DC 20036, *billdegrandis@paulhastings.com;* and Jenna L. McGrath, 2050 M Street NW, Washington, DC 20036, *jennamcgrath@paulhastings.com.*

A final decision will be made on the requested authorization after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or the reliability of the U.S. electric power supply system.

Copies of the Application will be made available, upon request, by accessing the program website at *https://energy.gov/node/11845,* or by emailing Matt Aronoff at *matthew.aronoff@hq.doe.gov.*

Signed in Washington, DC, on November 1, 2021.

Christopher Lawrence,

Management and Program Analyst, Electricity Delivery Division, Office of Electricity.

[FR Doc. 2021–24220 Filed 11–4–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension; Revision to Currently Approved Collection

AGENCY: Department of Energy.

ACTION: Submission for Office of Management and Budget (OMB) review; comment request.

SUMMARY: The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years, an information collection request with the OMB.

DATES: Comments regarding this collection must be received on or before December 6, 2021. If you anticipate difficulty in submitting comments within that period, contact the person listed below as soon as possible.

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 instrument and instructions should be directed by phone to Jonathan Parthum at (202) 586–5120 or by email at *jonathan.parthum@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the extended collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, 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 on respondents, including through the use of automated collection techniques or other forms of information technology.

This information collection request contains: (1) *OMB No.:* 1910–0800; (2) *Information Collection Request Title:* Legal Collections; (3) *Type of Review:* Renewal and Revision; (4) *Purpose:* To continue to maintain DOE oversight of responsibilities relating to DOE and Contractor invention reporting and related matters; (5) *Annual Estimated Number of Respondents:* 1525; (6) *Annual Estimated Number of Total*

Responses: 1830; (7) *Annual Estimated Number of Burden Hours:* 4412.4; (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $199,087.49.

The revision consists of updates to two documents: DOE F 482.2 and DOE F 2050.11. For DOE F 482.2, the form is modified to add a Patents Rights-Waiver Clause Including U.S. Competitiveness terms and conditions acceptance to the beginning of the document. As for DOE F 2050.11, this form is modified to add the appropriate Paperwork Reduction Act statement that is currently included in each of the other documents within the collection.

Statutory Authority: 42 U.S.C. 5908(a) (b) and (c); 37 CFR part 404; 10 CFR part 784.

Signing Authority: This document of the Department of Energy was signed on November 2, 2021, by Brian Lally, Assistant General Counsel for Technology Transfer and Intellectual Property, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect on this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 2, 2021.

Treena V. Garrett,

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

[FR Doc. 2021–24270 Filed 11–4–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–184–D]

Application To Export Electric Energy; Morgan Stanley Capital Group Inc.

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: Morgan Stanley Capital Group Inc. (Applicant or MSCG) has applied for authorization to transmit electric energy from the United States to Mexico pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before December 6, 2021.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to (202) 586–8008.

FOR FURTHER INFORMATION CONTACT: Matt Aronoff, (202) 586–5863, *matthew.aronoff@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electricity from the United States to a foreign country, pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 42 U.S.C. 7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On October 7, 2021, MSCG filed an application with DOE (Application or App.) to transmit electric energy from the United States to Mexico ''for a five-year period, or such longer period as the Department may authorize for similarly situated power marketers.'' App. at 1. MSCG states that it ''is a Delaware corporation with its principal place of business in New York, New York'' and that it ''is an indirect, wholly-owned subsidiary of Morgan Stanley.'' *Id.* at 2. MSCG represents that it ''does not directly own or control any electric generation or transmission facilities, nor does it hold a franchise or service territory for the transmission, distribution, or sale of electric power.'' *Id.* at 3.

MSCG states that it ''has purchased, or will purchase, the power that may be exported to Mexico from wholesale generators, electric utilities, and federal power marketing agencies.'' App. at 7. MSCG contends that its proposed export of electricity ''will not impair the sufficiency of electric supply within the United States, nor does it or will it impede or tend to impede the coordination in the public interest of facilities subject to the jurisdiction of the Federal Energy Regulatory Commission.'' *Id.* at 1–2.

The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning MSCG's application to export electric energy to Mexico should be clearly marked with OE Docket No. EA–184–D. Additional copies are to be provided directly to Edward Zabrocki, 1633 Broadway, 29th Floor, New York, NY 10019, *Ed.Zabrocki@morganstanley.com;* Daniel E. Frank, 700 Sixth St. NW, Suite 700, Washington, DC 20001–3980, *danielfrank@eversheds-sutherland.com;* and Martha M. Hopkins, 700 Sixth St. NW, Suite 700, Washington, DC 20001–3980, *martyhopkins@eversheds-sutherland.com.*

Copies of the Application will be made available, upon request, by accessing the program website at *https://energy.gov/node/11845,* or by emailing Matt Aronoff at *matthew.aronoff@hq.doe.gov.*

Signed in Washington, DC, on November 1, 2021.

Christopher Lawrence,

Management and Program Analyst, Electricity Delivery Division, Office of Electricity.

[FR Doc. 2021–24218 Filed 11–4–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–314–C]

Application To Export Electric Energy; BP Energy Company

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: BP Energy Company (Applicant or BP Energy) has applied for authorization to transmit electric energy from the United States to Mexico pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before December 6, 2021.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to (202) 586–8008.

FOR FURTHER INFORMATION CONTACT: Matt Aronoff, (202) 586–5863, *matthew.aronoff@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electricity from the United States to a foreign country, pursuant to

sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 42 U.S.C. 7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On October 20, 2021, BP Energy filed an application with DOE (Application or App.) to transmit electric energy from the United States to Mexico ''for a term of five (5) years, or the maximum period allowed.'' App. at 1. BP Energy states that it ''is a Delaware corporation and a wholly-owned indirect subsidiary of BP America Inc,'' which ''is an indirect, wholly-owned subsidiary of BP p.l.c. (''BP''), a company organized under the laws of England and Wales with its international headquarters in London, UK and its U.S. headquarters in Houston, Texas.'' *Id.* at 2. BP Energy represents that ''[n]either [it] nor any of its affiliates own or control electric transmission facilities except for those facilities that are necessary to connect generating facilities owned by affiliates to the transmission grid.'' *Id.* at 5.

BP Energy further claims that its proposed purchases will come from ''electric utilities, power marketers, federal power marketing agencies, and affiliated suppliers pursuant to voluntary agreements.'' App. at 5. BP Energy contends that its proposed exports ''do not and will not impair the sufficiency of the electric power supply within the United States.'' *Id.* at 5–6. BP Energy adds that its exports ''will not impede or tend to impede the regional coordination of electric utility planning or operations, but will instead conform to system requirements as they may change over time.'' *Id.* at 6.

The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning BP Energy's application to export electric energy to Mexico should be clearly marked with OE Docket No. EA–314–C. Additional copies are to be provided directly to Betsy Carr, 201 Helios Way, Houston, TX 77079, *betsy.carr@bp.com;* and Judy Briscoe, 201 Helios Way, Houston, TX 77079, *judy.briscoe@bp.com.*

Copies of the Application will be made available, upon request, by accessing the program website at *https://energy.gov/node/11845,* or by emailing Matt Aronoff at *matthew.aronoff@hq.doe.gov.*

Signed in Washington, DC, on November 1, 2021.

Christopher Lawrence,

Management and Program Analyst, Electricity Delivery Division, Office of Electricity.

[FR Doc. 2021–24219 Filed 11–4–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Notice of Availability of Draft Waste Incidental to Reprocessing Evaluation for the Test Bed Initiative Demonstration

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of availability.

SUMMARY: The U.S. Department of Energy (DOE) announces the availability of the *Draft Waste Incidental to Reprocessing Evaluation for the Test Bed Initiative Demonstration, U.S. Department of Energy* (Draft WIR Evaluation). The Draft WIR Evaluation concerns DOE's proposed Test Bed Initiative (TBI) Demonstration. Under the proposed TBI Demonstration, approximately 2,000 gallons of waste from tank SY–101 at the Hanford Site in Washington will be pretreated to remove most key radionuclides, then solidified (grouted) offsite and subsequently disposed of at a licensed and permitted disposal facility outside of the State of Washington. The Draft WIR Evaluation demonstrates that the pretreated and solidified waste will be incidental to reprocessing of spent nuclear fuel, will not be high-level radioactive waste (HLW), and may be managed as low-level radioactive waste (LLW). DOE prepared the Draft WIR Evaluation pursuant to DOE Order 435.1, *Radioactive Waste Management,* and DOE Manual 435.1–1, chg 3, *Radioactive Waste Management Manual.* DOE is consulting with the Nuclear Regulatory Commission (NRC) concerning the Draft WIR Evaluation. DOE is also making the Draft WIR Evaluation available for comments from States, Tribal Nations, stakeholders and the public. After consultation with NRC, carefully considering comments received, and performing any necessary revisions of analyses and technical documents, DOE plans to prepare a final WIR Evaluation. Based on the final WIR Evaluation, DOE may determine, in a future WIR Determination, whether the pretreated and solidified waste is incidental to reprocessing, is non-HLW, and may be managed as LLW.

DATES: DOE invites comments on the Draft WIR Evaluation during a 90-day comment period beginning November 5, 2021 and ending on February 2, 2022. DOE will consider all comments received by February 2, 2022. A public meeting on the Draft WIR Evaluation will be held on November 18, 2021. Before the meeting, DOE will issue stakeholder and media notifications and publish an additional notice in the local newspaper providing the date, time, and information concerning the public meeting.

ADDRESSES: Information on the public meeting date will be available before the meeting at the website listed in *https://www.hanford.gov/pageAction.cfm/calendar.* The Draft WIR Evaluation is available on the internet at *https://www.hanford.gov/page.cfm/ReprocessingEvaluationforBedInitiative.* Written comments should be submitted to: Ms. Jennifer Colborn, U.S. Department of Energy, Office of River Protection, 2440 Stevens Drive, Richland, WA 99354. Alternatively, comments may also be filed electronically by email to: *TBIWIR@rl.gov.*

FOR FURTHER INFORMATION CONTACT: For further information about this Draft WIR Evaluation, please contact Mr. Richard Valle by mail at U.S. Department of Energy, Office of River Protection, 2440 Stevens Drive, Richland, WA 99354, by phone at (509) 376–7256, or by email at *richard_j_valle@orp.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE currently stores radioactive waste in underground tanks at the Hanford Site in the State of Washington. The waste is managed as HLW generated, in part, by the prior reprocessing of spent nuclear fuel for defense-related activities during the Manhattan Project and Cold War eras. Hanford's current mission focuses on the cleanup and remediation of those wastes and ultimate closure of the site. As part of that mission, DOE is retrieving waste from the Hanford tanks, separating the low-activity waste (LAW) from other waste in the Hanford tanks and vitrifying (immobilizing in a glass matrix) some of the LAW. DOE has not selected a supplemental treatment method for the remaining LAW in the

Hanford tanks.[1] The proposed TBI Demonstration would demonstrate a potential supplemental LAW treatment approach.[2]

This Draft WIR Evaluation concerns approximately 2,000 gallons of waste from Hanford tank SY–101, which, under the proposed TBI Demonstration, will be pretreated at the Hanford Site to remove most key radionuclides, then solidified (grouted) offsite and disposed of at a licensed and permitted facility outside the State of Washington. This Draft WIR Evaluation evaluates whether the pretreated and solidified waste will be incidental to reprocessing of spent nuclear fuel, will not be HLW, and may be managed as LLW under the criteria in Section II.B.(2)(a) of the U.S. Department of Energy (DOE) Manual 435.1–1, *Radioactive Waste Management Manual.* This Draft WIR Evaluation demonstrates that the criteria in DOE Manual 435.1–1 will be satisfied.

For the proposed TBI Demonstration, about 2,000 gallons of Tank SY–101 supernate (the uppermost liquid layer of the tank waste that contains low levels of insoluble, long-lived radionuclides) will be pretreated using: In-tank settling, followed by decanting, filtering, and processing through ion exchange media. The decanting (pumping without disturbing the underlying saltcake layer), filtering and ion exchange pretreatment will take place within an In Tank Pretreatment System, installed in Tank SY–101. The pretreated liquid will be transferred into totes (Type A shipping packages). Trucks will transport the shipping packages to a commercial treatment facility, either Perma-Fix Northwest in Richland, Washington, Energy*Solutions,* near Clive, Utah, Perma-Fix Diversified Scientific Services Inc., in Kingston, Tennessee, or Waste Control Specialists LLC, near Andrews, Texas. At the offsite treatment facility, the waste will be solidified in a grout matrix. DOE plans to dispose of the treated and solidified waste as mixed LLW at either the Energy*Solutions* disposal facility near Clive, Utah or the Waste Control Specialists Federal Waste Facility (WCS FWF), near Andrews, Texas. At this time, DOE has not selected the location of either the solidification facility or the disposal facility.

Section II.B.(2)(a) of DOE Manual 435.1–1 sets forth criteria for determining, based on an evaluation, whether waste is incidental to reprocessing, is not HLW, and may be managed as LLW. Those criteria, in relevant part, are that the wastes: ''(1) have been processed, or will be processed, to remove key radionuclides to the maximum extent that is technically and economically practical; (2) will be managed to meet safety requirements comparable to the performance objectives, set out in 10 CFR part 61, subpart C, Performance Objectives; and (3) are to be managed, pursuant to DOE's authority under the Atomic Energy Act of 1954, as amended, in accordance with the provisions in Chapter IV [of Manual 435.1–1], provided the waste will be incorporated into a solid physical form at a concentration that does not exceed the applicable concentration limits for Class C LLW, as set out in 10 CFR 61.55, Waste Classification.''

This Draft WIR Evaluation demonstrates that the criteria in Section II.B.(2)(a) of DOE Manual 435.1–1 will be met. As to the first criterion, key radionuclides will be removed to the maximum extent technically and economically practical. Pretreatment will remove approximately 98.8% of the key radionuclides (including cesium-137 and its daughter, barium-137m) from the approximately 2,000 gallons of tank SY–101 supernate. About 1.8 curies will remain in the pretreated waste. Regarding the second criterion, the solidified waste will meet the waste acceptance criteria for the Energy*Solutions* disposal facility or the WCS FWF, as applicable, which will ensure that the performance objectives, including doses, will be met for LLW disposal as set forth in the *Utah Administrative Code* and the *Texas Administrative Code,* respectively, which are comparable to the NRC performance objectives at 10 CFR part 61, subpart C. With respect to the third criterion, the pretreated and grouted waste will be in a solid physical form, will be well below the concentration limits for Class C LLW, and is expected to meet concentration limits for Class A LLW.

DOE is consulting with the NRC concerning this Draft WIR Evaluation. DOE is also making this Draft WIR Evaluation available for comments by States, Tribal Nations, stakeholders and the public.

After consultation with the NRC, carefully considering comments received from States, Tribal Nations, stakeholders and the public, and performing any necessary revisions of analyses and technical documents, DOE plans to prepare a final WIR Evaluation. Based on the final WIR Evaluation, DOE may determine (in a future WIR Determination) whether the waste is incidental to reprocessing, is not HLW, and may be managed as LLW. If DOE issues a Final WIR Evaluation and WIR Determination in the future, then the pretreated LAW discharged from the tank—from which key radionuclides will have been removed to the maximum extent technically and economically practical—will be managed as LLW, subject to the analysis and commitments in the Final WIR Evaluation and WIR Determination.[3]

Signing Authority

This document of the Department of Energy was signed on October 29, 2021, by Mark A. Gilbertson, Associate Principal Deputy Assistant Secretary for Regulatory and Policy Affairs, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 2, 2021.

Treena V. Garrett,

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

[FR Doc. 2021–24213 Filed 11–4–21; 8:45 am]

BILLING CODE 6450–01–P

[1] See *Record of Decision for the Final Tank Closure and Waste Management Environmental Impact Statement for the Hanford Site, Richland, Washington.* 78 FR 75913 (Dec. 13, 2013).

[2] Implementation of the proposed TBI Demonstration is contingent upon completion of analysis and documentation required pursuant to the National Environmental Policy Act of 1969, as amended, 42 U.S.C. 4321, *et seq.* (NEPA). DOE prepared a Draft Environmental Assessment for the proposed TBI Demonstration, *Draft Environmental Assessment of the Test Bed Initiative Demonstration* (DOE/EA–2086) and provided it to the host and affected States and Indian Tribes, for a 14-day comment period, on August 17, 2021.

[3] It follows that such LLW will be appropriately stored, transported, solidified, and disposed of as LLW.

DEPARTMENT OF ENERGY

[Docket No. 21–99–LNG]

Carib Energy (USA) LLC; Application for Blanket Authorization To Export Previously Imported Liquefied Natural Gas to Non-Free Trade Agreement Countries on a Short-Term Basis

AGENCY: Office of Fossil Energy and Carbon Management, Department of Energy.

ACTION: Notice of application.

SUMMARY: The Office of Fossil Energy and Carbon Management (FECM) of the Department of Energy (DOE) gives notice (Notice) of receipt of an application (Application), filed on September 14, 2021, by Carib Energy (USA) LLC (Carib Energy). Carib Energy requests blanket authorization to export liquefied natural gas (LNG) previously imported into the United States by vessel from foreign sources in a volume equivalent to 0.48 billion cubic feet per year (Bcf/yr) of natural gas on a cumulative basis over a two-year period. Carib Energy filed the Application under the Natural Gas Act (NGA).

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures, and written comments are to be filed electronically as detailed in the Public Comment Procedures section no later than 4:30 p.m., Eastern time, December 6, 2021.

ADDRESSES:

Electronic Filing by email: fergas@hq.doe.gov.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, DOE has found it necessary to make temporary modifications to the comment submission process in light of the ongoing Covid-19 pandemic. DOE is currently accepting only electronic submissions at this time. If a commenter finds that this change poses an undue hardship, please contact Office of Resource Sustainability staff at (202) 586–2627 or (202) 586–4749 to discuss the need for alternative arrangements. Once the Covid-19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

FOR FURTHER INFORMATION CONTACT:

Beverly Howard or Jennifer Wade, U.S. Department of Energy (FE–34) Office of Regulation, Analysis, and Engagement, Office of Resource Sustainability, Office of Fossil Energy and Carbon Management,[1] Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–9387 or (202) 586–4749, *beverly.howard@hq.doe.gov* or *jennifer.wade@hq.doe.gov.*

Cassandra Bernstein, U.S. Department of Energy (GC–76) Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, Room 6D–033, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–9793, *cassandra.bernstein@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: Carib Energy requests a blanket authorization to export LNG that has been previously imported into the United States from foreign sources for a two-year period. Carib Energy states that it will purchase the LNG primarily from the Crowley LNG Puerto Rico Truck Loading Facility (Crowley Facility), located in Peñuelas, Puerto Rico.[2] Carib Energy states that the Crowley Facility will receive LNG that has been imported into Puerto Rico from locations outside the United States via the EcoElectrica LNG Terminal. Carib Energy proposes to export the LNG from the Crowley Facility by use of approved IM07/TVAC–ASME LNG containers (ISO containers) transported on ocean-going container vessels to any country within Central America, South America, or the Caribbean with which trade is not prohibited by U.S. law or policy.[3] This includes both countries with which the United States has entered into a free trade agreement (FTA) requiring national treatment for trade in natural gas (FTA countries) and all other countries (non-FTA countries). This Notice applies only to the portion of the Application requesting authority to export the previously imported LNG to non-FTA countries pursuant to section 3(a) of the NGA, 15 U.S.C. 717b(a).

Carib Energy requests that the authorization commence on the earlier of either the first date of re-export of LNG, or five years from the date on which DOE issues an order granting the requested authorization. Carib Energy further requests this authorization on its own behalf and as agent for other parties who hold title to the LNG at the time of export. Additional details can be found in Carib Energy's Application, posted on the DOE website at: *www.energy.gov/sites/default/files/2021-09/21-99-LNG.pdf.*

DOE Evaluation

In reviewing Carib Energy's Application, DOE will consider any issues required by law or policy. DOE will consider domestic need for the gas, as well as any other issues determined to be appropriate, including whether the arrangement is consistent with DOE's policy of promoting competition in the marketplace by allowing commercial parties to freely negotiate their own trade arrangements. Parties that may oppose this application should comment in their responses on these issues.

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.,* requires DOE to give appropriate consideration to the environmental effects of its proposed decisions. No final decision will be issued in this proceeding until DOE has met its NEPA responsibilities.

Public Comment Procedures

In response to this Notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable. Interested parties will be provided 30 days from the date of publication of this Notice in which to submit comments, protests, motions to intervene, or notices of intervention.

Any person wishing to become a party to the proceeding must file a motion to intervene or notice of intervention. The filing of comments or a protest with respect to the Application will not serve to make the commenter or protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the Application. All protests, comments, motions to intervene, or notices of intervention must meet the requirements specified by the regulations in 10 CFR part 590.

As noted, DOE is only accepting electronic submissions at this time. Please email the filing to *fergas@hq.doe.gov.* All filings must include a reference to ''Docket No. 21–99–LNG'' or ''Carib Energy Application'' in the title line.

Please Note: Please include all related documents and attachments (*e.g.,* exhibits) in the original email correspondence. Please do not include any active hyperlinks or password protection in any of the documents or attachments related to the filing. All electronic filings submitted to DOE must follow these guidelines to ensure that all documents are filed in a timely manner. Any hardcopy filing submitted greater in length than 50 pages must also include, at the time of the filing, a digital copy on disk of the entire submission.

The Application and any filed protests, motions to intervene, notices of

[1] The Office of Fossil Energy changed its name to the Office of Fossil Energy and Carbon Management on July 4, 2021.

[2] Carib Energy states that it is a wholly-owned subsidiary of Crowley Shipping, Inc. Carib Energy further states that Crowley LNG Puerto Rico constructed the Crowley Facility and owns and controls the site on which the Crowley Facility is located.

[3] *See also* Email from Greg Buffington, Crowley Shipping, to DOE, Docket No. 21–99–LNG (Oct. 26, 2021) (stating that Carib Energy proposes to export this LNG via ISO containers only).

interventions, and comments will also be available electronically by going to the following DOE Web address: *https://www.energy.gov/fecm/division-natural-gas-regulation.*

A decisional record on the Application will be developed through responses to this Notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final Opinion and Order may be issued based on the official record, including the Application and responses filed by parties pursuant to this Notice, in accordance with 10 CFR 590.316.

Signed in Washington, DC, on October 29, 2021.

Amy Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Resource Sustainability.

[FR Doc. 2021–24214 Filed 11–4–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL22–4–000]

Tri-State Generation and Transmission Association, Inc.; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On October 29, 2021, the Commission issued an order in Docket No. EL22–4–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e, instituting an investigation into whether Tri-State Generation and Transmission Association, Inc.'s methodology and procedures for determining a Contract Termination Payment is unjust, unreasonable, unduly discriminatory or preferential, or otherwise unlawful. *Tri-State Generation and Transmission Association, Inc., LLC,* 177 FERC ¶ 61,059 (2021).

The refund effective date in Docket No. EL22–4–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL22–4–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 (2020), within 21 days of the date of issuance of the order.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC 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 ''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. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Dated: November 1, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24260 Filed 11–4–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP19–193–000]

Columbia Gulf Transmission, LLC; Notice of Request for Extension of Time

Take notice that on October 26, 2021, Columbia Gulf Transmission, LLC (Columbia Gulf) requested that the Federal Energy Regulatory Commission (Commission) grant an extension of time, until November 15, 2022, in order to place the replacement facilities of the Mainline 100 and Mainline 200 Replacement Project (Project) into service, in Menifee and Montgomery Counties, Kentucky, as authorized as part of Columbia Gulf's Project in the November 15, 2019 Order Granting Certificate and Approving Abandonment [1] (November 15 Order). The November 15 Order required Columbia Gulf to complete construction and make the facilities available for service within one year of the order date.

On July 7, 2020, Columbia Gulf requested an extension of time until November 15, 2021 to place the replacement facilities into service, to allow additional time for the U.S. Department of Transportation (''DOT'') to reach a decision on Columbia Gulf's application for a special permit. The special permit would allow Columbia Gulf to operate the segments of Mainline 100 and 200 proposed for replacement as part of the Project at the current MAOP without pipe replacement work or further action to maintain compliance with DOT regulations. On August 6, 2020, the Commission granted Columbia Gulf an extension of time until November 15, 2021.

The special permit application Columbia Gulf submitted to DOT on October 15, 2019 has yet to receive a determination. In order to provide DOT with additional time necessary to make a determination on Columbia Gulf's special permit application, Columbia Gulf respectfully requests a further extension of time to and including November 15, 2022, to place the replacement facilities into service. Upon receipt of the special permit, Columbia Gulf would, pursuant to Rule 212 of the Rules of Practice and Procedures of the Commission, 18 CFR 385.212, Columbia Gulf would submit a Motion to Vacate the authorizations granted in the November 15 Order with respect to the Mainline 100 and Mainline 200 Replacement Project. If unsuccessful in obtaining the special permit, Columbia Gulf would notify the Commission of its intent to begin construction of the Project to comply with DOT requirements and submit a revision to its Implementation Plan reflecting an updated construction schedule.

This notice establishes a 15-calendar day intervention and comment period deadline. Any person wishing to comment on Columbia Gulf's request for an extension of time may do so. No reply comments or answers will be considered. If you wish to obtain legal status by becoming a party to the proceedings for this request, you should, on or before the comment date stated below, file a motion to intervene

[1] *Columbia Gulf Transmission, LLC,* 169 FERC ¶ 62,084 (2019).

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 Natural Gas Act (18 CFR 157.10).[2]

As a matter of practice, the Commission itself generally acts on requests for extensions of time to complete construction for Natural Gas Act facilities when such requests are contested before order issuance. For those extension requests that are contested,[3] the Commission will aim to issue an order acting on the request within 45 days.[4] The Commission will address all arguments relating to whether the applicant has demonstrated there is good cause to grant the extension.[5] The Commission will not consider arguments that re-litigate the issuance of the certificate order, including whether the Commission properly found the project to be in the public convenience and necessity and whether the Commission's environmental analysis for the certificate complied with the National Environmental Policy Act.[6] At the time a pipeline requests an extension of time, orders on certificates of public convenience and necessity are final and the Commission will not re-litigate their issuance.[7] The OEP Director, or his or her designee, will act on all of those extension requests that are uncontested.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFile'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern Time on November 16, 2021.

Dated: November 1, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–24229 Filed 11–4–21; 8:45 am]

BILLING CODE 6717–01–P

[2] Only motions to intervene from entities that were party to the underlying proceeding will be accepted. *Algonquin Gas Transmission, LLC,* 170 FERC ¶ 61,144, at P 39 (2020).

[3] Contested proceedings are those where an intervenor disputes any material issue of the filing. 18 CFR 385.2201(c)(1) (2019).

[4] *Algonquin Gas Transmission, LLC,* 170 FERC ¶ 61,144, at P 40 (2020).

[5] *Id.* at P 40.

[6] Similarly, the Commission will not re-litigate the issuance of an NGA section 3 authorization, including whether a proposed project is not inconsistent with the public interest and whether the Commission's environmental analysis for the permit order complied with NEPA.

[7] *Algonquin Gas Transmission, LLC,* 170 FERC ¶ 61,144, at P 40 (2020).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG22–16–000.
Applicants: Dunns Bridge Solar Center, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Dunns Bridge Solar Center, LLC.
Filed Date: 10/22/21.
Accession Number: 20211022–5209.
Comment Date: 5 p.m. ET 11/12/21.

Docket Numbers: EG22–17–000.
Applicants: Jackson Generation, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Jackson Generation, LLC.
Filed Date: 11/1/21.
Accession Number: 20211101–5116.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: EG22–18–000.
Applicants: MPH AL Pierce, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator status of MPH Al Pierce, LLC.
Filed Date: 10/29/21.
Accession Number: 20211029–5388.
Comment Date: 5 p.m. ET 11/19/21.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL22–6–000.
Applicants: LOUISIANA PUBLIC SERVICE COMMISSION v. ENTERGY CORPORATION, ENTERGY SERVICES, LLC, ENTERGY LOUISIANA, LLC, ENTERGY ARKANSAS, LLC, ENTERGY MISSISSIPPI, LLC, ENTERGY NEW ORLEANS, LLC, ENTERGY TEXAS, INC.
Description: Complaint of the Louisiana Public Service Commission.
Filed Date: 10/29/21.
Accession Number: 20211029–5333.
Comment Date: 5 p.m. ET 11/18/21.

Docket Numbers: EL22–7–000.
Applicants: Virginia Municipal Electric Association v. Virginia Electric and Power Co. d/b/a Dominion Virginia Power.
Description: Complaint of Virginia Municipal Electric Association against Virginia Electric and Power Company, doing business as Dominion Virginia Power.
Filed Date: 10/29/21.
Accession Number: 20211029–5350.
Comment Date: 5 p.m. ET 11/18/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER17–1428–005.
Applicants: Tilton Energy LLC.
Description: Informational Filing of Tilton Energy LLC pursuant to Schedule 2 of the MISO Tariff.
Filed Date: 10/22/21.
Accession Number: 20211022–5207.
Comment Date: 5 p.m. ET 11/12/21.

Docket Numbers: ER20–1006–003.
Applicants: DATC Path 15, LLC.
Description: Compliance filing: Amendment to 3000022 to be effective 6/13/2020.
Filed Date: 11/1/21.
Accession Number: 20211101–5249.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER21–2520–002.
Applicants: MATL LLP.
Description: Compliance filing: Order No. 676 Second Revised Compliance Filing to be effective 12/31/9998.
Filed Date: 11/1/21.
Accession Number: 20211101–5009.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER21–2581–001.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment: Deficiency Response in ER21–2581—City of Independence, Missouri Formula Rate to be effective 10/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5206.
Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER21–2652–000.
Applicants: Caddo Wind, LLC.
Description: Report Filing: Second Supplement to Application for Market-Based Rate Authority to be effective N/A.

Filed Date: 10/29/21.
Accession Number: 20211029–5280.
Comment Date: 5 p.m. ET 11/5/21.
Docket Numbers: ER21–2902–001.
Applicants: MATL LLP.
Description: Tariff Amendment: Amendment to Section 205 Filing Relating to Order 676 to be effective 12/31/9998.
Filed Date: 11/1/21.
Accession Number: 20211101–5010.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: ER22–291–000.
Applicants: PSEG Fossil LLC.
Description: Baseline eTariff Filing: Proposed Reactive Service Tariff—Essex Generation Station to be effective 12/1/2021.
Filed Date: 10/29/21.
Accession Number: 20211029–5336.
Comment Date: 5 p.m. ET 11/19/21.
Docket Numbers: ER22–292–000.
Applicants: Nexus Line, LLC.
Description: Initial rate filing: Nexus Line LLC TSA Rate Schedule 2 to be effective 12/31/9998.
Filed Date: 10/29/21.
Accession Number: 20211029–5341.
Comment Date: 5 p.m. ET 11/19/21.
Docket Numbers: ER22–293–000.
Applicants: Nexus Line, LLC.
Description: Initial rate filing: Nexus Line LLC Rate Schedule 3 Filing to be effective 12/31/9998.
Filed Date: 10/29/21.
Accession Number: 20211029–5345.
Comment Date: 5 p.m. ET 11/19/21.
Docket Numbers: ER22–294–000.
Applicants: PSEG Fossil LLC.
Description: § 205(d) Rate Filing: Reactive Service Tariff—Remainder of Generating Facilities to be effective 12/1/2021.
Filed Date: 10/29/21.
Accession Number: 20211101–5000.
Comment Date: 5 p.m. ET 11/19/21.
Docket Numbers: ER22–295–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Midcontinent Independent System Operator, Inc. Request for Approval of Recovery of Charges in Accordance with Schedule 34 of the Open Access Transmission, Energy and Operating Reserve Markets Tariff.
Filed Date: 10/29/21.
Accession Number: 20211029–5377.
Comment Date: 5 p.m. ET 11/19/21.
Docket Numbers: ER22–296–000.
Applicants: Jackson Generation, LLC.
Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization and Request for Waivers to be effective 11/2/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5101.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: ER22–297–000.
Applicants: Ameren Illinois Company.
Description: § 205(d) Rate Filing: Reimbursement Agreement—PPI Meppen Rate Schedule 157 to be effective 12/31/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5107.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: ER22–298–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2021–11–01_Att X Fuel Change filing to be effective 1/1/2022.
Filed Date: 11/1/21.
Accession Number: 20211101–5125.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: ER22–299–000.
Applicants: Duke Energy Progress, LLC.
Description: § 205(d) Rate Filing: DEP–FPWC Revised Rate Schedule No. 184 to be effective 1/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5131.
Comment Date: 5 p.m. ET 11/22/21.
Docket Numbers: ER22–300–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original NSA, Service Agreement 6210, Queue No. NQ16 to be effective 10/1/2021.
Filed Date: 11/1/21.
Accession Number: 20211101–5133.
Comment Date: 5 p.m. ET 11/22/21.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES22–17–000.
Applicants: PacifiCorp.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of PacifiCorp.
Filed Date: 10/27/21.
Accession Number: 20211027–5181.
Comment Date: 5 p.m. ET 11/17/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 1, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24256 Filed 11–4–21; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–286–000]

Dry Bridge Solar 2, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Dry Bridge Solar 2, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 22, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in

docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: November 1, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24263 Filed 11–4–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–289–000]

Dry Bridge Solar 4, 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 Dry Bridge Solar 4, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 22, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: November 1, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24265 Filed 11–4–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2221–041]

Empire District Electric Company; Notice of Material Amendment of License Application, Soliciting Comments and Associated Study Requests, and Establishing The Deadline for Submission of Final Amendments

On February 28, 2020, Empire District Electric Company (Empire District) filed, pursuant to sections 4(e) and 15 of the Federal Power Act, an application for a new major license to continue operating the Ozark Beach Hydroelectric Project No. 2221 (Ozark Beach Project) located on the White River in Taney County, Missouri. On March 10, 2020, the Commission issued a Notice of Application Tendered for Filing with the Commission and Establishing Procedural Schedule for Licensing and Deadline for Submission of Final Amendments. On August 28, 2020, Empire District filed an amendment to the license application.

The Ozark Beach Project currently occupies 5.1 acres of federal land administered by the U.S. Army Corps of Engineers (Corps) and is situated between two multipurpose projects owned by the Corps. The Corps' Table Rock Project, which is located approximately 22 miles upstream of the Ozark Beach Project, is operated in a peaking mode based on regional electrical demand requirements. The Ozark Beach Project discharges directly into the Corps' Bull Shoals Project reservoir, which is located immediately downstream.

The project currently consists of the following existing facilities: (1) A 2,224-acre reservoir (Lake Taneycomo) with a gross storage capacity of 21,800 acre-feet and a usable storage capacity of 6,500 acre-feet at a water surface elevation of 701.35 feet National Geodetic Vertical Datum of 1929 (NGVD29); (2) a 1,301-foot-long dam consisting of, from west to east: (a) A 420-foot-long earth fill embankment with a concrete core wall, (b) an 18-foot-long concrete overflow spillway topped with a sharp-crested steel weir having a compound section, (c) a 575-foot-long, 53-foot-high, concrete overflow spillway topped with 32 4-foot-high Obermeyer gates, (d) an 18-foot-long concrete non-overflow section, (e) an integral 220-foot-long reinforced concrete powerhouse, and (f) a 50-foot-long concrete non-overflow section; (3) a 220-foot-long, 88-foot-wide, 92-foot-high reinforced concrete

integral powerhouse with an operating head of 50 feet; (4) trash racks at the entrance to the intakes; (5) four 7,500 horsepower (5.625 megawatt (MW)) vertical-shaft Francis-type turbines with a total capacity of 30,000 horsepower (22.500 MW), each coupled to a 4.0 MW generator with a total installed capacity of 16.0 MW; (6) a 445-foot-long, 4,600-volt overhead transmission line connected to a three-phase, 4,600 to 161,000 volt step-up transformer with a rating of 22,400-kilovolt ampere that connects to Empire District's 161,000-volt transmission system; and (7) appurtenant facilities.

Using the storage in Lake Taneycomo, the Ozark Beach Project is currently operated based on various conditions including closely matching the releases of the Corps' upstream Table Rock Project, market pricing, Lake Taneycomo water level, the water level of the Corps' downstream Bull Shoals Project, and rainfall. The project currently operates to maintain water surface elevations between 701.35 and 700.00 feet NGVD29 in Lake Taneycomo. The Ozark Beach Project currently has an estimated annual energy production of about 50,768 megawatt-hours.

In its amended license application, Empire District proposes to replace the existing 4-foot-high Obermeyer gates with new 6-foot-high Obermeyer gates. As proposed, the water surface elevation of Lake Taneycomo would be raised from 701.35 to 703.35 feet NGVD29 when the 6-foot gates are fully raised. At a water surface elevation of 703.35 feet NGVD29, Lake Taneycomo would increase from 2,224 to 2,523 acres, its gross storage capacity would increase from 21,800 to 24,100 acre-feet, and its usable storage capacity would increase from 6,500 to 8,800 acre-feet. As amended, the project would operate between 703.35 and 700 feet NGVD29, the total generating capacity would remain 16.0 MW, and the estimated annual energy production would remain about 50,768 megawatt-hours.

The current project boundary for the project encompasses approximately 8,271 acres of water and land. Empire District proposes to modify the current project boundary by removing 5,728 acres for a proposed project boundary that encompasses 2,543 acres. Empire District's proposal would reduce the existing area of federal land occupied by the project from 5.1 acres to 0.64 acre.

Pursuant to 18 CFR 4.35(f)(1)(ii)(A), the license application as amended constitutes a material amendment. This application is not ready for environmental analysis at this time. With this notice, we are soliciting comments on Empire District's amended application as well as study requests. The deadline for filing comments and study requests is 60 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file comments and study requests using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the Comment 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 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–2221–041.

In addition to publishing the full text of this notice in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this notice, as well as other documents in the proceeding, 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 (P–2221). 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, (866) 208–3676 or (202) 502–8659 (TTY).

You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Applicant Contact: Randy Richardson, Plant Manager—Energy Center/Ozark Beach, Empire District Electric Company, 2537 Fir Road, Sarcoxie, MO 64862, (417) 625–6138 or *RRichardson@libertyutilities.com.*

FERC Contact: Colleen Corballis at (202) 502–8598 or email at *colleen.corballis@ferc.gov.*

The Council on Environmental Quality (CEQ) issued a final rule on July 15, 2020, revising the regulations under 40 CFR parts 1500–1518 that federal agencies use to implement NEPA (see Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act, 85 FR 43,304). The Final Rule became effective on and applies to any NEPA process begun after September 14, 2020. An agency may also apply the regulations to ongoing activities and environmental documents begun before September 14, 2020, which includes the proposed Ozark Beach Project. Commission staff intends to conduct its NEPA review in accordance with CEQ's new regulations.

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: November 1, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–24231 Filed 11–4–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER22–270–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to ISA, Service Agreement No. 5479; Queue No. AC1–145 to be effective 9/5/2019.

Filed Date: 10/29/21.

Accession Number: 20211029–5244.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–271–000.

Applicants: PacifiCorp.

Description: Tariff Amendment: Termination of NorthernGrid Funding Agreement Concurrence to be effective 12/31/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5249.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–272–000.

Applicants: Gulf Power Company.

Description: § 205(d) Rate Filing: Revised Depreciation Rates, Capital

Recovery Schedules, Dismantlement Accruals to be effective 1/1/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5254.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–273–000.

Applicants: Florida Power & Light Company.

Description: § 205(d) Rate Filing: FPL–LCEC RS 317 Revised Dep. Rates, Capital Recovery Schedules, and Dismantle to be effective 1/1/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5255.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–274–000.

Applicants: Idaho Power Company.

Description: § 205(d) Rate Filing: SA 430—Conditional Firm PTP with MEAI to be effective 1/1/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5261.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–275–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: NorthernGrid Funding Agreement Concurrence 2022–2023 to be effective 1/1/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5269.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–276–000.

Applicants: Florida Power & Light Company.

Description: § 205(d) Rate Filing: FPL–FKEC RS 322 Revised Dep. Rates, Capital Recovery Schedules, and Dismantle to be effective 1/1/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5272.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–277–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Rate Schedule No. 33 to be effective 12/31/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5274.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–278–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Rate Schedule No. 217 Exhibit B Revision to be effective 12/31/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5285.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–279–000.

Applicants: PSEG Keys Energy Center LLC.

Description: Baseline eTariff Filing: Proposed Reactive Service Tariff Filing to be effective 12/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5286.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–280–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: OATT Revised Attachment K—NorthernGrid Planning Process 2022 to be effective 1/1/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5288.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–281–000.

Applicants: Dry Bridge Solar 1, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 12/29/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5290.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–282–000.

Applicants: El Paso Electric Company.

Description: § 205(d) Rate Filing: EPE Notice of Rate Change to OATT, Revisions to Open Access Transmission Tariff to be effective 1/1/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5294.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–283–000.

Applicants: Idaho Power Company.

Description: § 205(d) Rate Filing: Attachment K—NVE attachments to be effective 1/1/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5299.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–284–000.

Applicants: MPH AL Pierce, LLC.

Description: Baseline eTariff Filing: Filing of Market-Based Rate Application to be effective 12/29/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5306.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–285–000.

Applicants: PSEG Fossil Sewaren Urban Renewal LLC.

Description: Baseline eTariff Filing: Proposed Reactive Service Tariff to be effective 12/1/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5310.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–286–000.

Applicants: Dry Bridge Solar 2, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 12/29/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5312.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–287–000.

Applicants: GridLiance West LLC.

Description: § 205(d) Rate Filing: GLW TRBAA 2022 Annual Update Filing to be effective 1/1/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5317.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–288–000.

Applicants: Dry Bridge Solar 3, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 12/29/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5320.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–289–000.

Applicants: Dry Bridge Solar 4, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 12/29/2021.

Filed Date: 10/29/21.

Accession Number: 20211029–5327.

Comment Date: 5 p.m. ET 11/19/21.

Docket Numbers: ER22–290–000.

Applicants: Oakland Power Company LLC.

Description: § 205(d) Rate Filing: Annual Reliability Must Run Agreement and Schedule F Informational Filings to be effective 1/1/2022.

Filed Date: 10/29/21.

Accession Number: 20211029–5328.

Comment Date: 5 p.m. ET 11/19/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24109 Filed 11–4–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–281–000]

Dry Bridge Solar 1, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Dry Bridge Solar 1, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 22, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: November 1, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24261 Filed 11–4–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–288–000]

Dry Bridge Solar 3, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Dry Bridge Solar 3, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 22, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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Dated: November 1, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24264 Filed 11–4–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER22–301–000.

Applicants: Dominion Energy South Carolina, Inc.

Description: § 205(d) Rate Filing: Attachment M Filing to be effective 1/1/2022.

Filed Date: 11/1/21.

Accession Number: 20211101–5140.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER22–302–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: Tariff Amendment: Notice of Cancellation of Rate Schedule No. 248 to be effective 12/31/2021.

Filed Date: 11/1/21.

Accession Number: 20211101–5146.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER22–303–000.

Applicants: Midcontinent Independent System Operator, Inc., ALLETE, Inc.

Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2021–11–01_ALLETE Inc Depreciation Rate Filing to be effective 1/1/2021.

Filed Date: 11/1/21.

Accession Number: 20211101–5163.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER22–304–000.

Applicants: AP Gas & Electric (NY), LLC.

Description: Compliance filing: Compliance Filing to be effective 12/31/2021.

Filed Date: 11/1/21.

Accession Number: 20211101–5170.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER22–305–000.

Applicants: Alabama Power Company.

Description: Tariff Amendment: Pinehurst Solar LGIA Termination Filing to be effective 11/1/2021.

Filed Date: 11/1/21.

Accession Number: 20211101–5173.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER22–306–000.

Applicants: Duke Energy Carolinas, LLC.

Description: § 205(d) Rate Filing: DEF—Revised Depreciation Rates Filing to be effective 1/1/2022.

Filed Date: 11/1/21.

Accession Number: 20211101–5189.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER22–307–000.

Applicants: Midcontinent Independent System Operator, Inc., Pioneer Transmission, LLC.

Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2021–11–01_Pioneer Attachment O Filing to be effective 1/1/2022.

Filed Date: 11/1/21.

Accession Number: 20211101–5197.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER22–308–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: SCE 2022 TRBAA Update to be effective 1/1/2022.

Filed Date: 11/1/21.

Accession Number: 20211101–5212.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER22–309–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to WMPA, Service Agreement No. 5108; Queue No. AC2–175 to be effective 10/28/2017.

Filed Date: 11/1/21.

Accession Number: 20211101–5216.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER22–310–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: 2022 RSBAA Update Filing to be effective 1/1/2022.

Filed Date: 11/1/21.

Accession Number: 20211101–5227.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER22–311–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: Second Amended GIA DSA Pomona Energy Storage WDT1250EXP WDT1510 SA No 859 860 to be effective 1/1/2022.

Filed Date: 11/1/21.

Accession Number: 20211101–5236.

Comment Date: 5 p.m. ET 11/22/21.

Docket Numbers: ER22–313–000.

Applicants: DATC Path 15, LLC.

Description: § 205(d) Rate Filing: Normal filing 2022 Appendix I to be effective 1/1/2022.

Filed Date: 11/1/21.

Accession Number: 20211101–5253.

Comment Date: 5 p.m. ET 11/22/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 1, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24259 Filed 11–4–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No.CP21–14–000]

Adelphia Gateway, LLC; Notice of Effectiveness of Withdrawal of Application

On December 7, 2020, Adelphia Gateway, LLC (Adelphia) filed a prior notice application to construct and operate a 3,000-horsepower compressor unit at its Marcus Hook Compressor Station in Delaware County, Pennsylvania. On October 12, 2021, Adelphia filed a notice of withdrawal of its application. No motion in opposition to the notice of withdrawal has been filed, and the Commission has taken no action to disallow the withdrawal. Pursuant to Rule 216(b) of the Commission's Rules of Practice and Procedure,[1] the withdrawal of the application became effective on October 28, 2021, and this proceeding is hereby terminated.

Dated: November 1, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–24230 Filed 11–4–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–284–000]

MPH AL Pierce, 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 MPH AL Pierce, 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

[1] 18 CFR 385.216(b) (2020).

to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 22, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: November 1, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–24262 Filed 11–4–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Salt Lake City Area Integrated Projects—Rate Order No. WAPA–199

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of rate order concerning fixed firm power rates.

SUMMARY: The fixed firm power rates for the Salt Lake City Area Integrated Projects (SLCA/IP) (Provisional Rates) have been confirmed, approved, and placed into effect on an interim basis. Based on the FY 2021 financial toll on the Upper Colorado River Basin Fund (Basin Fund) and the drought-impacted purchased power projections from the Bureau of Reclamation (Reclamation) *August 2021 24-Month Study* for FY 2022 and FY 2023 and the August 2021 Colorado River Simulation System (CRSS) traces for FY 2024 through FY 2026, existing rates will not sustain a balance in the Basin Fund capable of supporting operations. The Colorado River Storage Project Management Center (CRSP MC) of the Western Area Power Administration (WAPA) is implementing a new SLCA/IP firm power rate, effective December 1, 2021, through December 31, 2023.

DATES: The Provisional Rates under Rate Schedule SLIP–F12 are effective on the first day of the first full billing period beginning on or after December 1, 2021, and will remain in effect through December 31, 2023, pending confirmation and approval by the Federal Energy Regulatory Commission (FERC) on a final basis or until superseded.

FOR FURTHER INFORMATION CONTACT: Tim Vigil, CRSP Manager, Colorado River Storage Project Management Center, Western Area Power Administration, 1800 South Rio Grande Avenue, Montrose, CO 81401, or email: *CRSPMC-rate-adj-@wapa.gov,* or Thomas Hackett, Rates Manager, 801–524–5503, or email: *CRSPMC-rate-adj@wapa.gov.*

SUPPLEMENTARY INFORMATION: On December 17, 2020, FERC confirmed and approved Rate Schedules SLIP–F11 (SLCA/IP Firm Power), SP–NW5 (Network Integration Transmission Service), SP–PTP9 (Firm Point-to-Point Transmission Service), SP–NFT8 (Non-Firm Point-to-Point Transmission Service), SP–UU2 (Unreserved Use Penalties), SP–EI5 (Energy and Generator Imbalance Services), SP–SSR5 (Operating Reserves—Spinning and Supplemental Reserve Services), and SP–SS1 (Sale of Surplus Products) under Rate Order No. WAPA–190 (WAPA–190) on a final basis through September 30, 2025.[1]

WAPA published a **Federal Register** notice (Proposed FRN) on June 28, 2021 (86 FR 34002), proposing modifications to only the firm power rate schedule (SLIP–F11) established under WAPA–190. CRSP MC did not propose any changes to the transmission and ancillary services rate schedules established under WAPA–190, and they remain effective under WAPA–190 through September 30, 2025. The Proposed FRN also initiated a public consultation and comment period and set forth the date and location of the public information and public comment forums.

WAPA is implementing the firm power rate under Rate Schedule SLIP–F12 to address worsening drought conditions in the southwestern United States and volatile purchased power costs. The rates will go into effect December 1, 2021, and remain in effect until December 31, 2023, or until WAPA supersedes or changes the rates through another public rate process pursuant to 10 CFR part 903, whichever occurs first. The CRSP MC is only implementing the rate for 25 months to continue collaborative conversations with customers and interested parties on the most effective use of available generation and long-term strategies for managing the cost of purchased power. CRSP MC is basing FY 2022 and FY 2023 energy sales in the rate-setting Power Repayment Study (PRS) on the Reclamation *August 2021 24-month Study,* and FY 2024 through FY 2026 sales on the CRSS traces and is forgoing purchased power in the rates. Forgoing purchased power decreased the projected rate increase from 50 percent to 11 percent. CRSP MC will not be purchasing firming power to meet Sustainable Hydropower (SHP) levels as it has in the past. Calculated sales for the effective period of the rate will be limited to forecasted generation, referred to as the Deliverable Sales Amount (DSA). The DSA levels will be updated quarterly and provided to customers for power scheduling and billing purposes. These quarterly updates do not impact the rates. CRSP MC will firm to the DSA level if necessary. For those customers who elect, CRSP MC will offer Western Replacement Firming (WRF) purchased power to customers, as a pass-through cost at market rates, to firm to SHP levels. Customers electing not to take WRF will receive the DSA.

Legal Authority

By Delegation Order No. 00–037.00B, effective November 19, 2016, the Secretary of Energy delegated: (1) The authority to develop power and transmission rates to the WAPA Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the

[1] Order Confirming and Approving Rate Schedules on a Final Basis, FERC Docket No. EF20–7–000, 173 FERC ¶ 61,230 (2020).

Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, or to remand or disapprove such rates, to FERC. By Delegation Order No. S1–DEL–S4–2021, effective February 25, 2021, the Acting Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Under Secretary for Science (and Energy). By Redelegation Order No. S4–DEL–OE1–2021, effective March 25, 2021, the Acting Under Secretary for Science (and Energy) redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Assistant Secretary for Electricity. By Redelegation Order No. 00–002.10–05, effective July 8, 2020, the Assistant Secretary for Electricity further redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to WAPA's Administrator. This redelegation order, despite predating the February 2021 and March 2021 delegations, remains valid. This rate action is issued under Redelegation Order No. 00–002.10–05 and Department of Energy procedures for public participation in rate adjustments set forth at 10 CFR part 903.[1]

Following review of CRSP MC's proposal, I hereby confirm, approve, and place Rate Order No. WAPA–199, which provides the fixed rates for firm power, into effect on an interim basis. WAPA will submit Rate Order No. WAPA–199 to FERC for confirmation and approval on a final basis.

Department of Energy

Administrator, Western Area Power Administration

In the Matter of:

Western Area Power Administration, Colorado River Storage Project Management Center, Rate Adjustment for the Salt Lake City Area, Integrated Projects Fixed Firm Power Rates

Rate Order No. WAPA–199

Order Confirming, Approving, and Placing the Salt Lake City Area Integrated Projects Fixed Firm Power Rates Into Effect on an Interim Basis

The fixed rates in Rate Order No. WAPA–199 are established following section 302 of the Department of Energy (DOE) Organization Act (42 U.S.C. 7152).[1]

By Delegation Order No. 00–037.00B, effective November 19, 2016, the Secretary of Energy delegated: (1) The authority to develop power and transmission rates to the Western Area Power Administration's (WAPA) Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve on a final basis, remand, or disapprove such rates to FERC. By Delegation Order No. S1–DEL–S4–2021, effective February 25, 2021, the Acting Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Under Secretary for Science (and Energy). By Redelegation Order No. S4–DEL–OE1–2021, effective March 25, 2021, the Acting Under Secretary for Science (and Energy) redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Assistant Secretary for Electricity. By Redelegation Order No. 00–002.10–05, effective July 8, 2020, the Assistant Secretary for Electricity further delegated the authority to confirm, approve, and place such rates into effect on an interim basis to WAPA's Administrator. This redelegation order, despite predating the February 2021 and March 2021 delegations remains valid. This rate action is issued under Redelegation Order No. 00–002.10–05 and DOE procedures for public participation in rate adjustments set forth at 10 CFR part 903.[1]

Acronyms, Terms, and Definitions

As used in this Rate Order No. WAPA–199, the following acronyms, terms, and definitions apply:

Basin Fund: Upper Colorado River Basin Fund.

Capacity: The electric capability of a generator, transformer, transmission circuit, or other equipment. It is expressed in kilowatts (kW) or megawatts (MW).

Capacity Rate: The rate which sets forth the charges for capacity. It is expressed in dollars per kilowatt-month and applied to each kilowatt delivered to each Customer.

CDP: Customer Displacement Power.

Composite Rate: The Power Repayment Study (PRS) rate for commercial firm power, which is the total annual revenue requirement for capacity and energy divided by the total annual energy sales. It is expressed in mills per kilowatt-hour and used only for comparison purposes.

CRC: Cost Recovery Charge.

CROD: Contract Rate of Delivery. The maximum amount of capacity made available to a preference Customer for a period specified under a contract.

Customer: Firm electric service customer(s) contractually receiving SLCA/IP power and energy.

CY: Calendar Year. When used in the CRC it is the 12-month period the CRC is in effect.

DSA: Deliverable Sales Amount—marketable generation level, above which WAPA will forgo purchased power.

Energy Rate: The rate which sets forth the charges for energy. It is expressed in mills/kWh and applied to each DSA kWh delivered to each Customer.

Firm: A type of product or service available at the time requested by the Customer.

FY: Fiscal Year, October 1 to September 30.

GWh: Gigawatt-hour—the electrical unit of energy that equals 1 billion watthours or 1 million kWh.

Integrated Projects: The resources and revenue requirements of the Collbran, Dolores, Rio Grande, and Seedskadee projects blended with the CRSP to create the SLCA/IP resources and rate.

kW: Kilowatt—the electrical unit of capacity that equals 1,000 watts.

kWh: Kilowatt-hour—the electrical unit of energy that equals 1,000 watts in 1 hour.

kWmonth: Kilowatt-month—the electrical unit of the monthly amount of capacity.

MAF: Million Acre-Feet. The amount of gallons of water required to cover 1 million acres, 1 foot in depth.

Mill: A monetary denomination of the United States that equals one tenth of a cent or one thousandth of a dollar.

Mills/kWh: Mills per kilowatt-hour—the unit of charge for energy.

MW: Megawatt—the electrical unit of capacity that equals 1 million watts or 1,000 kilowatts.

MWh: One million watt-hours of electric energy. A unit of electrical energy which equals 1 megawatt of power used for 1 hour.

NEPA: National Environmental Policy Act of 1969, as amended.

OASIS: Open Access Same-Time Information System—An electronic posting system that a service provider maintains for transmission access data that allows all Customers to view information simultaneously.

O&M: Operations and Maintenance.

OM&R: Operations, Maintenance and Replacements.

[1] 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

[1] This Act transferred to, and vested in, the Secretary of Energy the power marketing functions of the Secretary of the Department of the Interior and the Bureau of Reclamation (Reclamation) under the Reclamation Act of 1902 (ch. 1093, 32 Stat. 388), as amended and supplemented by subsequent laws, particularly section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)); and other acts that specifically apply to the project(s) involved.

[1] 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

Power: Capacity and energy.

Project Use: Power used to operate SLCA/IP and CRSP facilities under Reclamation Law.

Provisional Rate: A rate confirmed, approved, and placed into effect on an interim basis by the Secretary or his/her designee.

Rate Brochure: A document prepared for public distribution explaining the rationale and background for the information contained in this rate order.

Ratesetting PRS: The Power Repayment Study (PRS) used for the rate adjustment period.

Revenue Requirement: The revenue required to recover O&M expenses, purchased power and transmission service expenses, interest, deferred expenses, and repayment of Federal investments, or other assigned costs.

SHP: Sustainable Hydropower (long-term SLCA/IP hydro capacity with energy).

SLCA/IP: Salt Lake City Area Integrated Projects.

WL: Waiver Level.

Work Plan: An estimate of costs that are expected to become the Congressional Budget for WAPA and Reclamation. Also known as a Work Program.

WRF: Western Replacement Firming.

WRP: Western Replacement Power.

Effective Date

The Provisional Rate Schedule SLIP–F12 will take effect on the first day of the first full billing period beginning on or after December 1, 2021, and will remain in effect through December 31, 2023, pending approval by FERC on a final basis or until superseded.

Public Notice and Comment

The CRSP MC followed the *Procedures for Public Participation in Power and Transmission Rate Adjustments and Extensions,* 10 CFR part 903, in developing these fixed rates. Following are the steps CRSP MC took to involve interested parties in the rate process:

1. On June 28, 2021, a **Federal Register** notice (86 FR 34002) (Proposal FRN) announced the proposed rates and launched the 65-day public consultation and comment period. The comment period was reduced from the customary 90-day period due to the $20 million financial impact of not implementing the rate by December 1, 2021.

2. On June 28, 2021, CRSP MC notified Customers and interested parties of the proposed rates and provided a copy of the published Proposal FRN.

3. On July 7, 2021, CRSP MC held a virtual public information forum. CRSP MC representatives explained the proposed fixed rates, answered questions, and gave notice that more information was available in the Rate Brochure.

4. On July 28, 2021, CRSP MC held a virtual public information forum on purchased power and WRF. CRSP MC representatives explained the process used to project purchase power, how WRF will be implemented, answered questions, and gave notice that more information would be available in a subsequent version of the Rate Brochure and provided points of contact for additional questions on WRF implementation.

5. On July 29, 2021, CRSP MC held a virtual public information forum on the CRC. CRSP MC representatives explained the purpose of the CRC, the need for changes, how it is calculated and implemented, answered questions, and gave notice that more information was available in the Rate Brochure.

6. On August 11, 2021, CRSP MC held a virtual public comment forum. This provided Customers and other interested parties an opportunity to provide official comments for the record.

7. On August 13, 2021, CRSP MC posted responses to questions asked during the August 11, 2021, virtual public comment forum on the rate action website and notified the Customers and interested parties via email.

8. CRSP MC provided a website that contains all dates, Customer letters, presentations, FRNs, Rate Brochure, and other information about this rate process. The rate action website is located at *www.wapa.gov/regions/CRSP/rates/Pages/rate-order-199.aspx.*

9. During the 65-day consultation and comment period, which ended on August 31, 2021, CRSP MC received 10 oral comments at the August 11, 2021, virtual public comment forum, and seven comment letters. All comments from the virtual public comment forum were addressed by WAPA via email and/or responses were posted to the rate action website on August 13, 2021. The comments and CRSP MC responses are addressed in the Comments section and have been considered in the preparation of this Rate Order No. WAPA–199.

Oral comments were received from the following organizations:

Colorado River Energy Distributors Association (CREDA)
Utah Associated Municipal Power Systems (UAMPS)
Arizona Electric Power Cooperative (AEPCO)

Written comments were received from the following organizations:

Colorado River Energy Distributors Association (CREDA)
Arizona Electric Power Cooperative (AEPCO)
Municipal Energy Agency of Nebraska (MEAN/NMPP)
Platte River Power Authority (PRPA)
Tri-State Generation and Transmission Association, Inc. (TRI–STATE)
Utah Rural Electric Cooperative Association (URECA)
Utah Municipal Power Agency (UMPA)

10. CRSP MC received comments on the original Rate Brochure. Comments were addressed in subsequent versions of the Rate Brochure.

11. CRSP MC provided a second consultation and comment period from September 22 through October 6, 2021. This comment period facilitated Customer feedback in reference to purchased power and generation updates. The comments and CRSP MC responses are addressed in the Comments section, and all comments have been considered in the preparation of this Rate Order No. WAPA–199.

Written comments were received from the following organizations:

Colorado River Energy Distributors Association (CREDA)
Platte River Power Authority (PRPA)

Power Repayment Study—Firm Power Service Rate Discussion

CRSP MC prepares PRSs each FY to determine if revenues will be sufficient to repay, within the required time, all costs assigned to the SLCA/IP. Repayment criteria are based on applicable laws and legislation, as well as policies including DOE Order RA 6120.2. To meet the cost recovery criteria outlined in DOE Order RA 6120.2, a revised PRS and rate adjustment have been developed to demonstrate that sufficient revenues will be collected under the Provisional Rate to meet future obligations. The revenue requirement and composite rate for SLCA/IP firm power service are being increased, as indicated in Table 1:

TABLE 1—COMPARISON OF REVENUE REQUIREMENTS AND COMPOSITE RATES

Firm power service	Existing requirements (October 1, 2020)	Provisional requirements (December 1, 2021)	Percent change
Revenue Requirement (million $)	$173.511	$181,197	+4.4
Composite Rate (mills/kWh)	27.45	30.51	+11.1

Under the existing rate methodology, rates for firm power service are designed to recover an annual revenue requirement that includes power investment repayment, aid to irrigation repayment, interest, O&M, replacements, and other expenses within the allowable period.

Firm Power Service—Existing and Provisional Rates

CRSP MC is implementing this rate action primarily in response to a large increase in purchased power costs due to worsening drought conditions in the southwestern United States and an increase to OM&R expenses.

CRSP MC is basing sales in the rate on forecasted generation in Reclamation's *August 2021 24-month Study* for the effective period of the rate and is subsequently forgoing purchased power in the Ratesetting PRS. Forgoing purchased power mitigates the projected rate increase from 50-percent down to 11-percent. CRSP MC will not automatically purchase firming power to SHP levels. For those Customers who elect, CRSP MC will purchase WRF power as a pass-through cost, at market rates, up to SHP levels. CRSP MC will purchase power to firm to the forecasted generation level, referred to as the DSA. The DSA will be updated quarterly as shown in Table 2. Customers will have at least 14 days to affirmatively select WRF for each quarter. Quarterly notices provide flexibility in responding to changes in hydrology and will not impact the rates. Customers can elect the full quarter or specific months within the quarter.

TABLE 2—QUARTERLY DSA ADJUSTMENT SCHEDULE

Quarter impacted	Reclamation 24-month study	Notify customers by:
December 2021	August 2021	mid-October 2021.
January–March 2022	November 2021	Est: November 20, 2021.
April–June 2022	February 2022	Est: February 20, 2022.
July–September 2022	May 2022	Est: May 20, 2022.
October–December 2022	August 2022	Est: August 20, 2022.
January–March 2023	November 2022	Est: November 20, 2022.
April–June 2023	February 2023	Est: February 20, 2023.
July–September 2023	May 2023	Est: May 20, 2023.
October–December 2023	August 2023	Est: August 20, 2023.

CRSP MC provided information on the implementation process of the WRF and DSA in the Rate Brochure, at the virtual public information forum, at a virtual purchased power forum, and replied to questions from the virtual public comment forum via email. This information was published on the rate action website at: *www.wapa.gov/regions/CRSP/rates/Pages/rates.aspx.*

A comparison of the existing and provisional rates for firm power service is listed in Table 3. The Provisional Rate is a fixed rate that will go into effect December 1, 2021, and remain in effect through December 31, 2023, or until WAPA supersedes or changes the rates through another public rate process pursuant to 10 CFR part 903, whichever occurs first.

TABLE 3—COMPARISON OF EXISTING AND PROVISIONAL RATE

Firm power service	Existing charges under rate schedule SLIP–F11 as of October 1, 2020	Provisional charges under rate schedule SLIP–F12 as of December 1, 2021	Percent change
Firm Energy Rate (mills/kWh)	11.43	12.36	+8.1
Firm Capacity Rate ($/kWmonth)	4.85	5.25	+8.3

Statement of Revenue and Related Expenses

Table 4 provides a comparison of the average annual expense data for the firm power service revenue requirement through the rate-setting period. The purchase power shown in the table reflects purchase power costs for October and November 2021 that fall under the SLIP F11 rates. There is no projected purchase power amount included in the rate for service from December 2021 through December 2026.

TABLE 4—ANNUAL REVENUE REQUIREMENTS AND FIRM POWER RATES COMPARISON TABLE

	Existing rate ($000)	Provisional rate ($000)	Difference ($000)
Rate Setting Period	2021–2038	2022–2045	

TABLE 4—ANNUAL REVENUE REQUIREMENTS AND FIRM POWER RATES COMPARISON TABLE—Continued

	Existing rate ($000)	Provisional rate ($000)	Difference ($000)
Revenue Distribution:			
Expenses:			
O&M	$97,352	$103,095	$5,743
Purchase Power	1,119	833	(286)
Transmission	8,998	8,984	(14)
Integrated Projects requirements	6,485	7,043	558
Interest	6,066	6,207	141
Other	17,909	13,547	(4,362)
Total Expenses	137,928	139,709	1,781
Principal Payments:			
Capitalized Expenses (deficits)	0	838	838
Replacements	26,918	29,581	2,663
Original Project and Additions	2,484	1,846	(638)
Irrigation	6,181	9,223	3,042
Total Principal Payments	35,583	41,488	5,905
Annual Revenue Requirement	173,511	181,197	7,686

The rates would provide sufficient revenue to recover annual O&M expenses, replacement expenses, interest expense, irrigation assistance, and capital repayment requirements within the cost recovery criteria set forth in Department of Energy (DOE) Order No. RA 6120.2.

Purchased power required to supplement hydropower deliveries up to contractual levels will be passed through to Customers under a separate charge, WRF, which would be in addition to the rate for hydropower deliveries. Any Customer not receiving WRF will not be charged the purchased power charge and would receive its proportionate amount of the DSA capacity and energy from WAPA each month.

SLCA/IP Firm Power Rate

The revenue requirement for Rate Schedule SLIP–F12 is based on current data available, specifically the FY 2020 historical financial data, FY 2022 Work Plan for WAPA, FY 2023 Work Plan for Reclamation, and Reclamation's *August 2021 24-Month Study* (24-month Study) and Colorado River Simulation System (CRSS) traces.

Under rate schedule SLIP–F12, WAPA will use the Reclamation *August 2021 24-Month Study* to determine generation and projected sales for the 2 rate years (FYs 22–23) and CRSS for FYs 24–26 of the rate-setting period. Additionally, the rate schedule includes actions WAPA will take should Lake Powell's water level drop below the level at which power can be generated.

Cost Recovery Charge

WAPA will retain the CRC as a mechanism to use, if necessary, to adequately recover and maintain a sufficient balance in the Basin Fund in the event projected expenses significantly exceed projected revenue estimates. The Basin Fund is a revolving fund that operates using CRSP MC power revenues without annual appropriations. The CRC is an additional surcharge on all long-term energy sales provided under the WAPA SLCA/IP firm electric service contracts. The CRC may be implemented when, among other things, the Basin Fund cash balance is at risk due to low hydropower generation, high prices for firming power, or emergency capitalized investment funding. The CRC is independent of the SLCA/IP PRS calculations.

WAPA reserves the right to implement a CRC at any point throughout the year using guidance from the existing implementation criteria in Table 5 and the latest 24-month Study from Reclamation. An established CRC would be in effect for 12 months from the date implemented. If circumstances dictate the need to reassess an established CRC, the updated CRC will supersede the previous CRC and remain in effect for 12 months. The CRC is implemented at WAPA's discretion based on the balance of the Basin Fund and WAPA's ability to meet contractual requirements. The minimum Basin Fund carryover balance is $40 million.

TABLE 5—CRC IMPLEMENTATION TIERS

Tier	Criteria, if the basin fund beginning balance is:	Notification
i	Greater than $150 million with an expected decrease to below $75 million	Annually (July).
ii	Less than $150 million but greater than $120 million with an expected 50-percent decrease in the next CY.	
iii	Less than $120 million but greater than $90 million with an expected 40-percent decrease in the next CY.	
iv	Less than $90 million but greater than $60 million with an expected 25-percent decrease in the next CY.	Semi-Annual (July/January).
v	Less than $60 million but greater than $40 million with an expected decrease to below $40 million in the next CY.	Monthly.

WAPA reserves the right to implement a CRC throughout the year if annual water releases from Glen Canyon Dam fall below 8.23 MAF, regardless of the Basin Fund balance.

If a CRC is implemented, CRSP MC will establish an energy Waiver Level (WL) using the CRC formula. Customers could accept either the CRC or WL. The WL provides WAPA the ability to reduce purchase power expenses by delivering less energy than its contractual obligations. For those Customers who agree to schedule no more energy than their proportionate share of the WL, WAPA would waive the CRC for that year.

If, in any month, the annual water release volumes from Glen Canyon Dam return to 8.23 MAF or higher while a CRC is in place, a new CRC will be calculated for the next month, and each Customer will be notified of the recalculated CRC results.

CRC sample calculations, narratives, and schedules are located on the CRC web page: *www.wapa.gov/regions/CRSP/rates/Pages/cost-recovery-charge.aspx.*

Comments

CRSP MC received 52 oral or written comments during the public consultation and comment period. The comments expressed have been paraphrased or consolidated, where appropriate, without compromising the meaning of the comments.

Comments on Firm Power Rates

A. *Comment:* Commentor urged WAPA to continue to refine elements other than purchased power in the PRS to result in the lowest possible rate, consistent with sound business principles.

Response: CRSP MC analyzed data including O&M work plans, 10-year plans for capital investment, and Customer agreements, as well as Customer input, to ensure rates are the lowest possible consistent with sound business principles.

B. *Comment:* Commentor requested that WAPA continue to reflect ''expense reductions to the work plans as they become available,'' until the latest possible date, as those work plan-related discussions are still underway.

Response: CRSP MC incorporated changes to the Reclamation and WAPA work plan reviews into the power repayment study as the information was made available including using WAPA's FY 22 Work Plan instead of the FY 23 Work Plan. CRSP MC updated supporting data documents and posted them to the rate action website and included the results in the Rate Brochure updates.

C. *Comment:* Multiple commentors asked about the availability of firm transmission for Customers who do not elect WRF and what CRSP MC will do with surplus transmission.

Response: The CROD capacity will not be reduced. Available capacity up to the CROD is available for Customer use as WRP and CDP as provided in the Customers' SLCA/IP firm electric service contracts. Surplus transmission, if any, would be made available through the OASIS based on existing policy and procedures.

D. *Comment:* Commentor expressed concerns over ''rate shock'' for small Customers and stated the rate process provides very little time for Customers to design and implement retail rate adjustments that account for these changes. Commentor believes WAPA must consider this rate shock and what (if any) new value WAPA can provide to help offset this significant increase.

Response: CRSP MC understands that increasing rates impacts its Customers. CRSP MC operates on a cost-basis and must establish rates to collect sufficient revenue to meet operational expense and repayment obligations. Significant increases in purchase power costs warrant the need for the rate action. CRSP MC followed public notice requirements of the Administrative Procedure Act in setting forth this proposed rate change. CRSP MC implemented this short rate period so collaborative conversations with interested parties could occur over the next 2 years on the most effective use of available generation and long-term strategies for managing the cost of purchased power.

Comments on Services

A. *Comment:* Commentor believes WAPA's Customers must have the ability to convert some of their allocation into ancillary services to offset the financial impacts of the rate increase.

Response: All available energy is committed to firm power service deliveries.

B. *Comment:* One commentor asked WAPA to clarify whether the firm capacity and energy will be restored to Customers in the event the Colorado River Basin's hydrological conditions revert to historical levels.

Response: Should forecasted hydrological conditions improve, the DSA levels will rise providing additional energy allocations for Customers. AHP as defined in the SLCA/IP firm electric service contract will also be offered if hydrological conditions improve significantly within an established quarter.

C. *Comment:* One commentor does not agree with WAPA's position that the ''Tribe under the benefit crediting contract would need to decide whether to receive WRF and communicate that decision to its benefit crediting utility.'' Commentor's position is the election of WRF should be that of the benefit crediting utility, not the Tribe.

Response: CRSP MC has clarified this issue. WRF may be selected by the utility providing the benefit crediting service. This is like the existing treatment under the WRP program. The benefit crediting amount provided to a Tribe is to be calculated on the Tribe's hydropower delivery amounts.

D. *Comment:* Commentor asked that WAPA ensure participants retain the option to independently purchase replacement power to cover shortfalls in CRSP production. The proposed opt-in process should be, at most, seasonal (every 6 months) to prevent adverse selection issues or last-minute decisions by individual members that change market conditions for all project participants.

Response: Customers can independently use their own resources or purchase their own firming power under the CDP program. To provide greater flexibility in responding to hydrology, CRSP MC has enhanced the DSA and WRF programs by using quarterly notices to the Customers. Although 6-month periods were originally proposed, Customers requested additional flexibility in determining which months to potentially purchase WRF. Quarterly notices will provide Customers additional flexibility in meeting their resource needs and provide CRSP MC more certainty about water releases and hydropower generation availability.

E. *Comment:* Commentor asked that WAPA protect preference Customers' firm transmission rights, so Customers can use their transmission rights for power delivered to make up for power WAPA cannot provide. Commentor asked that WAPA maintain the current practice for firm transmission for power delivered in lieu of WAPA power, which was implemented earlier in this ongoing drought.

Response: Available capacity up to the CROD is still available for Customer use as WRP and CDP.

Comments in Support

A. *Comment:* Multiple commentors provided favorable comments thanking WAPA for its willingness to collaborate through rate, resource, and work plan processes; inclusion of two topical

virtual public forums to assist in Customer review and understanding of the WAPA–199 rate; appreciation for WAPA's Customer notification of materials being posted on the rate website; appreciation for WAPA's willingness to work with them to improve the capability and accessibility of the modeling tools used to analyze and produce CRSP rate scenarios in a timely manner; appreciation for WAPA's flexibility in providing a 14-day consultation and comment period after ''final purchased power amounts'' have been posted to its website; appreciation towards WAPA, CRSP staff, and Reclamation's work with Customers during this rate process and through the process referred to as the ''work program review'' process.

Response: CRSP MC appreciates the feedback and recognizes the benefits of collaborating with Customers and interested parties.

B. *Comment:* Two commentors expressed appreciation for CRSP MC's and Upper Colorado Region of Reclamation's approach to mitigating drought impacts and ensuring that the Basin Fund remains viable through the new rate components and continuation of the WRP and CDP processes, as well as the PRS and rates.

Response: CRSP MC appreciates the feedback.

C. *Comment:* Commentor expressed support for the revisions made to the CRC described in the Rate Brochure.

Response: CRSP MC appreciates the feedback on the CRC revisions.

Comments on Customer Communications

A. *Comment:* Two commentors requested WAPA continue timely communication, collaboration, and transparency with CRSP Customers on decisions, ongoing concerns, and potential impacts of recent Senate infrastructure funding.

Response: While the Senate infrastructure funding is out of scope for this rate action, CRSP MC understands the benefits of communication, collaboration, and transparency with its Customers in addressing potential rate impacts.

B. *Comment:* One commentor requested WAPA incorporate information/adjustments from pending Reclamation and WAPA reviews into the final proposed/provisional rate, and the results of that inclusion be provided to them.

Response: CRSP MC incorporated changes tied to the Reclamation and WAPA work plan reviews into the PRS as the information was made available. CRSP MC updated supporting data documents, posted them to the rate action website, and included the results in the Rate Brochure updates.

C. *Comment:* One commentor requested WAPA ensure Customers are notified of the Provisional Rate under this rate order prior to the issuance of Customer Notification of the DSA Season Update for Winter 2022 Season.

Response: CRSP MC provided the projected final rate on September 22, 2021, when it opened the *Customer Comment Period on Purchased Power and Generation.* The rate was subsequently decreased based on changes to project use power and CRSP MC's decision to use the FY 2022 work plan for the rate-setting period to reduce costs.

D. *Comment:* Commenter requested their most recent correspondence be included in the WAPA–199 record.

Response: CRSP MC filed all received comments in the decision of record for this rate process.

E. *Comment:* One commentor asked WAPA to continue its practice of collaboration and transparency for future decisions that affect CRSP Customers, such as costs for shaping and firming services as additional power is needed to maintain reliable supply.

Response: CRSP MC will continue its practice of collaboration and transparency.

Comments on Other

A. *Comment:* Commentor expressed recognition of the significance of the current drought conditions in the Colorado River Basin and the challenges that are being presented to WAPA and the CRSP Customers.

Response: CRSP MC appreciates the feedback.

B. *Comment:* One commentor expressed appreciation that the current scope of this rate order does not propose changes to ancillary services. Commentor wants any future changes to ancillary services to be part of a separate rulemaking.

Response: The current transmission and ancillary service formula rates established under Rate Order WAPA–190 required no modifications and continue to be effective under Rate Order WAPA–190 through September 30, 2025.

Second Comment Period Comments

A. *Comment:* Commenters expressed that it does not make sense to apply the CRC to all SHP and DSA because DSA is a subset of SHP.

Response: CRSP MC concurs. Since CRSP MC is only purchasing firming power to the DSA level, instances of SHP in the CRC will be replaced with DSA in the FRN and supporting documentation.

B. *Comment:* Commenters expressed that the CRC does not belong in the WRF cost recovery equation.

Response: CRSP MC concurs that WRF is exempt from the CRC calculation. The CRC only applies to the firming purchases up to the DSA level.

C. *Comment:* Commenter said, ''Because any portion of a customer's SHP above DSA will necessarily be WRF, the CRC should not apply to the above-DSA amount.''

Response: CRSP MC concurs that the CRC only applies to firming purchases up to the DSA level and made conforming changes within the FRN and supporting documentation.

D. *Comment:* Commenter thanks WAPA for the additional comment period to respond to updated elements of its CRSP rate proposal, and for its continuing commitment to transparency and collaboration in the rate-setting process.

Response: WAPA appreciates the feedback.

E. *Comment:* Commenter supports WAPA making ''additional changes to the work plan'' . . . and including them in the final rate package without ''an additional comment period for Customer review.''

Response: The WAPA decision not to initiate an additional comment period was due to the changes decreasing the proposed rate. Had the recent update to the workplan increased the proposed rate, WAPA would have considered an additional comment period or delayed implementation of the change until the next rate action.

F. *Comment:* Commenter supports the change in the DSA and WRF to quarterly time frames, and the addition that Customers may elect specific months within the quarter, to receive WRF.

Response: CRSP MC appreciates the feedback.

G. *Comment:* Commenter urges ongoing customer collaboration to address hydrologic conditions and forecasts, Basin Fund targets (including any methodology changes which may be made), MOA transfer timing, non-power program and non-reimbursable funding and Congressional action.

Response: CRSP MC recognizes the benefits of customer collaboration in dealing with the drought and impacts on generation and the energy rates. CRSP MC will continue its practice of transparency by providing information as it becomes available.

H. *Comment:* Commenter supports the collaborative effort WAPA has made

with Customers to develop long-term solutions to manage revenue requirements and cash flow.

Response: WAPA appreciates the feedback and recognizes the benefits of customer collaboration.

Certification of Rates

I have certified that the Provisional Rates for SLCA/IP Firm Power under Rate Schedule SLIP–F12 are the lowest possible rates, consistent with sound business principles. The Provisional Rates were developed following administrative policies and applicable laws.

Availability of Information

Information about this rate adjustment, including the Rate Brochure, PRSs, comments, letters, memoranda, and other supporting materials that were used to develop the Provisional Rates, is available for inspection and copying at the Colorado River Storage Project Management Center Office, 1800 South Rio Grande Avenue, Montrose, CO. Many of these documents are also available on WAPA's website at *www.wapa.gov/regions/CRSP/rates/Pages/rates.aspx,* or email; *CRSPMC-rate-adj@wapa.gov.*

Ratemaking Procedure Requirements

Environmental Compliance

WAPA has determined this action fits within the following categorical exclusions listed in appendix B to subpart D of 10 CFR part 1021.410: B4.3 (Electric power marketing rate changes) and B4.4 (Power marketing services and activities). Categorically excluded projects and activities do not require preparation of either an environmental impact statement or an environmental assessment.[1] Specifically, WAPA has determined that this rulemaking is consistent with activities identified in B4, Categorical Exclusions Applicable to Specific Agency Actions (see 10 CFR part 1021, appendix B to subpart D, part B4). A copy of the categorical exclusion determination is available on WAPA's website at: *www.wapa.gov/regions/CRSP/environment/Pages/environment.aspx.*

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Submission to the Federal Energy Regulatory Commission

The Provisional Rate herein confirmed, approved, and placed into effect on an interim basis, together with supporting documents, will be submitted to FERC for confirmation and final approval.

Order

In view of the above, and under the authority delegated to me, I hereby confirm, approve, and place into effect, on an interim basis, Rate Order No. WAPA–199. The rates will remain in effect on an interim basis until: (1) FERC confirms and approves them on a final basis; (2) subsequent rates are confirmed and approved; or (3) such rates are superseded.

Signing Authority

This document of the Department of Energy was signed on October 28, 2021, by Tracey LeBeau, Administrator, Western Area Power Administration, pursuant to delegated authority from the Secretary of Energy. That document, with the original signature and date, is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 2, 2021.

Treena V. Garrett

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

Rate Schedule SLIP–F12

(Supersedes Rate Schedule SLIP–F11)

United States Department of Energy

Western Area Power Administration

Colorado River Storage Project Management Center Salt Lake City Area Integrated Projects

Schedule of Rates for Firm Power Service (Approved Under Rate Order No. WAPA–199)

Effective: The first day of the first full billing period beginning on or after December 1, 2021, and extending through December 31, 2023, or until superseded by another rate schedule, whichever occurs earlier.

Available: In the area served by the Salt Lake City Area Integrated Projects.

Applicable: To the wholesale power Customer for firm power service supplied through one meter at one point of delivery or as otherwise established by contract.

Character: Alternating current, 60 hertz, three-phase, delivered and metered at the voltages and points established by contract.

Monthly Rate: Demand Charge: $5.25 per kilowatt of billing demand.

Energy Charge: $12.36 mills per kilowatthour of use of Deliverable Sales Amount (DSA) energy.

Modification of Purchased Power: WAPA will not automatically provide purchased power to firm to SHP energy allocations, nor will there be any purchased power costs under Rate Order WAPA–199 in the rate setting period in the power repayment study under Rate Order WAPA–199. WAPA will establish the rates using the projected DSA data in the Bureau of Reclamation's (Reclamation) *August 2021 24-month Study* and Reclamation's August 2021 Colorado River Simulation System traces.

Western Replacement Firming (WRF): WRF applies to pass-through purchased power costs for energy provided between the DSA level and SHP energy allocation. WRF is an optional product. Customers must elect quarterly, and may elect specific months within the quarter, to receive WRF. The charge for this purchased power will be determined at the time of the purchase based on market rates. There are no losses or an administrative fee charged to WRF. A schedule for the quarterly updates is in the rate brochure on the rate action website: *www.wapa.gov/regions/CRSP/rates/Pages/rates.aspx.*

Billing Demand: The billing demand will be the greater of:

1. The highest 30-minute integrated demand measured during the month up to, but not more than, the delivery obligation under the power sales contract, or,

2. The Contract Rate of Delivery.

Billing Energy: The billing energy will be the energy measured during the month up to, but not more than, the delivery obligation under the power sales contract.

Adjustment for Transformer Losses: If delivery is made at transmission voltage but metered on the low-voltage side of the substation, the meter readings will be increased to compensate for transformer losses as provided in the contract.

Adjustment for Power Factor: The Customer will be required to maintain a power factor at all points of

[1] The determination was done in compliance with NEPA (42 U.S.C. 4321–4347); the Council on Environmental Quality Regulations for implementing NEPA (40 CFR parts 1500–1508); and DOE NEPA Implementing Procedures and Guidelines (10 CFR part 1021).

measurement between 95 percent lagging and 95 percent leading.

Adjustment for Western Replacement Power (WRP): Pursuant to the Customer's Firm Electric Service Contract, as amended, WAPA will bill the Customer for its proportionate share of the costs of WRP within a given time. WAPA will include in the monthly power bill the cost of the WRP, and the incremental administrative costs associated with WRP.

Adjustment for Customer Displacement Power (CDP) Administrative Charges: WAPA will include in the Customer's regular monthly power bill the incremental administrative costs associated with CDP.

Adjustment for Minimum Power Pool: If Lake Powell drops below ''minimum power pool'' and power cannot be generated, WAPA will provide 30 days' notice to the Customers prior to reducing the DSA.

Cost Recovery Charge (CRC): To adequately recover and maintain a sufficient balance in the Basin Fund, WAPA uses a cost recovery mechanism, called a CRC. The CRC is a charge on all long-term energy sales provided under WAPA's SLCA/IP firm electric service contracts.

This charge will be, at a minimum, recalculated before July 1 of each year, and WAPA will provide notification to the Customers consistent with the procedures in 10 CFR 903. WAPA has the discretion to implement the CRC at any point throughout the year using the criteria in Table 1. The charge, if needed, will be placed into effect on the first day of the first full-billing period beginning on or after the first day of the month the CRC is implemented. For the purposes of the CRC, the 12-month period of a CRC will be described as a calendar year (CY). The CRC will be calculated as follows:

TABLE 1—CRC TIERS

Tier	Criteria, if the basin fund beginning balance (BFBB) is:	Notification
i	Greater than $150 million, with an expected decrease to below $75 million	Annually (July).
ii	Less than $150 million but greater than $120 million, with an expected 50 percent decrease in the next CY.	
iii	Less than $120 million but greater than $90 million, with an expected 40 percent decrease in the next CY.	
iv	Less than $90 million but greater than $60 million, with an expected 25 percent decrease in the next CY.	Semi-Annual (July/January).
v	Less than $60 million but greater than $40 million with an expected decrease to below $40 million in the next CY.	Monthly.

CRC sample calculations, narratives, and schedules showing the dates for implementing a CRC throughout the year are located at the CRC web page: *www.wapa.gov/regions/CRSP/rates/Pages/cost-recovery-charge.aspx.*

Waiver Level (WL)

WAPA will establish a WL that provides WAPA the ability to reduce purchased power expenses by scheduling less energy than what is contractually required. Therefore, for those Customers who voluntarily schedule no more energy than their proportionate share of the WL, WAPA will waive the CRC for that year. After the Funds Available have been determined, the WL will be set at the sum of the energy that can be provided through hydro generation and purchased with Funds Available. The WL will not be less than the forecasted Hydro Energy.

Trigger for Water Release Criteria: In the event that Reclamation's 24-month study projects Glen Canyon Dam water releases will drop below 8.23 million acre feet (MAF) in a water year (October through September), WAPA will recalculate the CRC to include those lower estimates of hydropower generation. WAPA, as in the yearly projection for the CRC, will give the Customers a 45-day notice to request a waiver of the CRC if they do not want to have the CRC charge added to their energy bills. This recalculation will remain in effect for the remainder of the CY.

If the annual water release volumes from Glen Canyon Dam return to 8.23 MAF or higher during the trigger implementation, a new CRC will be calculated for the next month, and the Customer will be notified.

Trigger for New Rate Criteria

WAPA would reassess an implemented CRC when a new rate goes into effect to determine if the implemented CRC should be continued, superseded, or terminated.

Prior Year Adjustment for CRC: Since the annual determination of the CRC is based upon estimates, an annual, prior-year adjustment (PYA) will be calculated for those who did not elect the waiver level. The PYA will be based on the 12-month period the CRC was in effect.

The Customers' PYA will be based on their prior 12-months' energy multiplied by the PYA mills/kWh to determine the dollar value that will be assessed. The Customer will be charged or credited for this dollar amount equally in the remaining months of the next 12-month billing cycle. WAPA will complete this calculation within 2 months of the end of the CRC. Therefore, if the PYA is calculated in June, the charge/credit will be spread over the remaining 9 months of the CY (July through March).

Adjustment for CRC Waiver: Customers can choose not to take the full DSA energy supplied as determined in the attached formulas for CRC and will be billed the Energy and Capacity rates listed above, but not the CRC.

[FR Doc. 2021–24217 Filed 11–4–21; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–SFUND–2014–0549; FRL–8990–01–OLEM; OMB Control Number 2050–0077]

Proposed Information Collection Request; Comment Request; Application for Reimbursement to Local Governments for Emergency Response to Hazardous Substance Releases Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Section 123 (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), Application for Reimbursement to Local Governments for Emergency Response to Hazardous Substance Releases under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Section 123 (Renewal) (EPA ICR Number 1425.12, OMB Control Number 2050–0077) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, the EPA is soliciting public comments on specific aspects of the proposed information collection as described in Supplementary Information. This is a proposed extension of the ICR, which is currently approved through May 31, 2022. 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.

DATES: Comments must be submitted on or before January 4, 2022.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–SFUND–2014–0549 to: (1) EPA online using *www.regulations.gov* (our preferred method), by email to *superfund.docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Brian Schlieger, Office of Emergency Management, Mail Code 5104A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–3128; email address: *schlieger.brian@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *http://www.regulations.gov.* Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room is closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. For further information about the EPA's public docket, Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.* The telephone number for the Docket Center is 202–566–1744.

Pursuant to section 3506(c)(2)(A) of the PRA, the EPA is soliciting comments and information to enable it to: (i) 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; (ii) 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; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) 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. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: The Agency requires applicants for reimbursement under this program authorized under Section 123 of CERCLA to submit an application that demonstrates consistency with program eligibility requirements. This is necessary to ensure proper use of the Superfund. EPA reviews the information to ensure compliance with all statutory and program requirements. The applicants are local governments who have incurred expenses, above and beyond their budgets, for hazardous substance response. Submission of this information is voluntary and to the applicant's benefit.

The burden estimates, numbers and types of respondents, wage rates and unit and total costs for this ICR renewal will be revised and updated, if needed, during the 60-day comment period while the ICR Supporting statement is undergoing review at OMB.

Form Numbers: 9310–1.

Respondents/affected entities: Entities potentially affected by this action are local governments that apply for reimbursement under this program.

Respondents' obligation to respond: voluntary (CERCLA Section 123).

Estimated total number of respondents: 20.

Frequency of response: On occasion.

Estimated total annual burden: 170 hours.

Estimated total annual costs: $4,392.80. This includes an estimated burden cost of $25.84/hour and there are no capital investment or maintenance and operational costs.

Changes in the estimates: Despite the increase in hourly rate, because the estimated total number of applications per year and the estimated burden hours per application have decreased, the overall burden has decreased by $602.20. The decrease in hours per application is because the form can be filled and submitted electronically.

Dated: October 28, 2021.

Donna K. Salyer,

Director, Office of Emergency Management.

[FR Doc. 2021–24288 Filed 11–4–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9059–2]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed October 25, 2021 10 a.m. EST Through November 1, 2021 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its

comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20210164, Draft, FERC, WY, Clear Creek Expansion Project, Comment Period Ends: 12/20/2021, Contact: Office of External Affairs 866–208–3372.

EIS No. 20210165, Final, CHSRA, CA, Burbank to Los Angeles Project Section Final Environmental Impact Report/Environmental Impact Statement, Review Period Ends: 12/06/2021, Contact: Scott Rothenberg 916–403–6936.

EIS No. 20210166, Final, FHWA, AZDOT, AZ, Sonoran Corridor Tier 1 Final Environmental Impact Statement and Record of Decision, Contact: Ammon Heier 602–382–8983. Under 23 U.S.C. 139(n)(2), FHWA has issued a single document that consists of a final environmental impact statement and record of decision. Therefore, the 30-day wait/review period under NEPA does not apply to this action.

EIS No. 20210167, Final, FERC, LA, Alberta Xpress and Lease Capacity Abandonment Projects, Review Period Ends: 12/06/2021, Contact: Office of External Affairs 866–208–3372.

Dated: November 1, 2021.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2021–24212 Filed 11–4–21; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

Sunshine Act Meetings; Notice of Open Meeting of the Sub-Saharan Africa Advisory Committee of the Export-Import Bank of the United States (EXIM)

TIME AND DATE: Thursday, November 18, 2021 from 1:30 p.m.–4:30 p.m. EDT.

PLACE: The meeting will be held virtually.

STATUS: *Public Participation:* The meeting will be open to public participation and time will be allotted for questions or comments submitted online. Members of the public may also file written statements before or after the meeting to *external@exim.gov.* Interested parties may register for the meeting at *https://teams.microsoft.com/registration/PAFTuZHHMk2Zb1GDkIVFJw,5M1LfonJMEi2VFUgYRv6oQ,i145n2l9vkmDj5btNlkuGw,-6CRfLLz6kGUqdmww26IRw,ttxm8vm0qUKagOb0ZrYcTg,NRlkaqExP0mJNzPZfdZNzQ?mode=read&tenantId=b953013c-c791-4d32-996f-518390854527.*

MATTERS TO BE CONSIDERED: Discussion of EXIM policies and programs designed to support the expansion of financing support for U.S. manufactured goods and services in Sub-Saharan Africa.

CONTACT PERSON FOR MORE INFORMATION: For further information, contact India Walker, External Engagement Specialist at 202–480–0062.

Joyce B. Stone,

Assistant Corporate Secretary.

[FR Doc. 2021–24334 Filed 11–3–21; 11:15 am]

BILLING CODE 6690–01–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Renewal of Federal Accounting Standards Advisory Board Charter

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

SUMMARY: Notice is hereby given that under the authority and in furtherance of the objectives of agency regulations, the Secretary of the Treasury, the Director of the Office of Management and Budget, and the Comptroller General of the United States (the sponsors) have agreed to continue an advisory committee to consider and recommend accounting standards and principles for the federal government. Copies can be obtained by contacting FASAB at (202) 512–7350.

FOR FURTHER INFORMATION CONTACT: Ms. Monica R. Valentine, Executive Director, 441 G Street NW, Suite 1155, Washington, DC 20548, or call (202) 512–7350.

Authority: 31 U.S.C. 3511(d), the Federal Advisory Committee Act, as amended (5 U.S.C. App.).

Dated: October 28, 2021.

Monica R. Valentine,

Executive Director.

[FR Doc. 2021–24235 Filed 11–4–21; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Privacy Act of 1974; System of Records

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice of a New System of Records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, notice is given that the Board of Governors of the Federal Reserve System (Board) proposes to establish a new system of records, entitled BGFRS–44, ''FRB—Public Health and Safety System.'' This system of records maintains information collected in response to a public health emergency, such as a pandemic or disaster, or other health and safety concerns when necessary to ensure a safe and healthy environment for Board employees, contractors, and other individuals who work for the Board.

DATES: Comments must be received on or before December 6, 2021. This new system of records will become effective December 6, 2021, without further notice, unless comments dictate otherwise.

The Office of Management and Budget (OMB), which has oversight responsibility under the Privacy Act, requires a 30-day period prior to publication in the **Federal Register** in which to review the system and to provide any comments to the agency. The public is then given a 30-day period in which to comment, in accordance with 5 U.S.C. 552a(e)(4) and (11).

ADDRESSES: You may submit comments, identified by *BGFRS–44 ''FRB—Public Health and Safety System,''* by any of the following methods:

- *Agency website: https://www.federalreserve.gov.* Follow the instructions for submitting comments at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include name and number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments will be made available on the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons or to remove sensitive personally identifiable information. Public comments may also be viewed electronically and printed in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays.

FOR FURTHER INFORMATION CONTACT: David B. Husband, Senior Counsel, (202) 530–6270, or *david.b.husband@frb.gov;* or Mary Bigloo, Senior Counsel, (202) 475–6361, or *mary.bigloo@frb.gov;*

Legal Division, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

SUPPLEMENTARY INFORMATION: The Board is establishing this system of records under the Privacy Act of 1974. The Board is committed to providing Board employees, contractors, and other individuals who work for the Board with a safe and healthy environment. To ensure and maintain the safety of these individuals in response to a public health emergency, such as a pandemic or disaster, or other health and safety concerns, the Board may develop and institute safety measures that necessitate the collection of personal information.

These measures may require individuals who work for the Board to provide relevant medical and health information. This information could include information about potential or confirmed exposures to communicable diseases or hazardous agents or materials. This information may also include, for example, test results for communicable diseases and information about vaccination status for communicable diseases (including attestations of vaccination status as well as proof of vaccination), information about requests for exemptions by Board employees and others who work for the Board from vaccination requirements and the basis for such requests (such as religious beliefs or medical conditions). In the case of suspected or confirmed exposures to communicable diseases or hazardous agents or materials occurring either at Board facilities, events, or elsewhere during the conduct of official Board business, the Board may also collect contact tracing information in order to trace exposed individuals and notify such individuals and public health authorities to prevent further exposure.

SYSTEM NAME AND NUMBER:

BGFRS–44, ''FRB—Public Health and Safety System''

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

SYSTEM MANAGER(S):

John Forbes, Program Manager, Employee Life, Human Resources, Management Division, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551, (202) 974–7052, or *john.b.forbes@frb.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sections 10 and 11 of the Federal Reserve Act (12 U.S.C. 243, 244, and 248).

PURPOSE(S) OF THE SYSTEM:

These records are collected and maintained to aid in efforts to protect and safeguard the premises, grounds, property, personnel, and operations of the Board and to ensure and maintain the health and safety of Board employees, contractors, and other individuals who work for the Board in response to a public health emergency, such as a pandemic or disaster, or other health and safety concerns.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Past and present Board employees, contractors, and other individuals who work for the Board.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system maintains information collected about Board employees, contractors, and other individuals who work for the Board in response to a public health emergency, such as a pandemic or disaster, or other health and safety concerns. The information collected about these individuals may include but is not limited to:

(a) Biographical and personal information, such as name, contact information, whether the individual is in a high-risk category or has a household member, relative, or close associate that is in a high-risk category, and dates and locations of recent travel;

(b) Health information including, but not limited to, medical symptoms, temperature checks, expected or confirmed test results, potential or actual exposure to a communicable disease or hazardous agent or material, immunization and vaccination information or records, and other relevant medical information and history;

(c) Information necessary to conduct contact tracing that includes, but is not limited to, the dates and times the individual was on-site at Board facilities, the locations the individual accessed (*e.g.,* office and cubicle number), and whether they may have potentially come into close contact with individuals who have probable or confirmed diagnoses of communicable diseases or exposures to hazardous agents or materials; and

(d) Attestations and proof of vaccination status as well as information relating to requests to be exempt from a vaccination requirement, including the basis for the request, medical information related to the request, and all information related to the Board's response to the request.

RECORD SOURCE CATEGORIES:

Information is generally provided by the individual to whom the record pertains, the individual's medical provider, or other system or entity that may retain relevant medical information such as a state vaccination registry or commercial entity that maintains medical or vaccination information. Information is also collected from security systems monitoring access to Board facilities or events, such as video surveillance and turnstiles, human resources systems, emergency notification systems, and federal, state, and local agencies assisting with the response to a public health emergency or similar health and safety concerns. Information may also be collected from companies responsible for managing the Board's leased office or event spaces or from third parties in the course of the Board's contact tracing activities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

General routine uses A, B, C, D, F, G, H, I, and J apply to this system. These general routine uses are located at *https://www.federalreserve.gov/files/SORN-page-general-routine-uses-of-board-systems-of-records.pdf* and are published in the **Federal Register** at 83 FR 43872 at 43873–74 (August 28, 2018). In addition, records may also be disclosed:

(a) To federal agencies such as the U.S. Department of Health and Human Services, state and local health departments, and other public health or cooperating medical authorities in connection with program activities and related collaborative efforts to deal more effectively with exposures to communicable diseases and other health hazards, and to satisfy mandatory reporting requirements when applicable.

(b) To appropriate federal, state, local, tribal, foreign governmental agencies or multilateral governmental organizations, or Federal Reserve Banks, to the extent permitted by law, and in consultation with legal counsel, for the purpose of protecting the interests of a Board employee, contractor, or other individual, including to assist such agencies or organizations in preventing exposure to or transmission of a communicable disease or to combat other significant public health threats.

(c) To any individual when necessary to trace suspected or confirmed

exposures to communicable diseases or hazardous agents or materials that are the subject of a public health emergency or similar health and safety concerns at Board facilities, Board events, or elsewhere during the conduct of official Board business and to notify exposed individuals.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Paper records in this system are stored in locked file cabinets with access limited to staff with a need to know. Electronic records are stored on a secure server with access limited to staff with a need to know.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by name or other identifying aspects.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The retention for these records is currently under review. Until review is completed, the records in the system will not be destroyed.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Paper records are secured by lock and key and electronic files are stored on secure servers. The system has the ability to track individual user actions within the system. The audit and accountability controls are based on NIST and Board standards which, in turn, are based on applicable laws and regulations. The controls assist in detecting security violations and performance or other issues in the system. Access to the system is restricted to authorized users who require access for official business purposes. Users are classified into different roles and common access and usage rights are established for each role. User roles are used to delineate between the different types of access requirements such that users are restricted to data that is required in the performance of their duties. Periodic assessments and reviews are conducted to determine whether users still require access, have the appropriate role, and whether there have been any unauthorized changes.

RECORD ACCESS PROCEDURES:

The Privacy Act allows individuals the right to access records maintained about them in a Board system of records. Your request for access must: (1) Contain a statement that the request is made pursuant to the Privacy Act of 1974; (2) provide either the name of the Board system of records expected to contain the record requested or a concise description of the system of records; (3) provide the information necessary to verify your identity; and (4) provide any other information that may assist in the rapid identification of the record you seek.

Current or former Board employees may make a request for access by contacting the Board office that maintains the record. The Board handles all Privacy Act requests as both a Privacy Act request and as a Freedom of Information Act request. The Board does not charge fees to a requestor seeking to access or amend his/her Privacy Act records.

You may submit your Privacy Act request to the—Secretary of the Board, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

You may also submit your Privacy Act request electronically through the Board's FOIA ''Electronic Request Form'' located here: *https://www.federalreserve.gov/secure/forms/efoiaform.aspx.*

CONTESTING RECORD PROCEDURES:

The Privacy Act allows individuals to seek amendment of information that is erroneous, irrelevant, untimely, or incomplete and is maintained in a system of records that pertains to them. To request an amendment to your record, you should clearly mark the request as a ''Privacy Act Amendment Request.'' You have the burden of proof for demonstrating the appropriateness of the requested amendment and you must provide relevant and convincing evidence in support of your request.

Your request for amendment must: (1) Provide the name of the specific Board system of records containing the record you seek to amend; (2) identify the specific portion of the record you seek to amend; (3) describe the nature of and reasons for each requested amendment; (4) explain why you believe the record is not accurate, relevant, timely, or complete; and (5) unless you have already done so in a related Privacy Act request for access or amendment, provide the necessary information to verify your identity.

NOTIFICATION PROCEDURES:

Same as ''Access procedures'' above. You may also follow this procedure in order to request an accounting of previous disclosures of records pertaining to you as provided for by 5 U.S.C. 552a(c).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY: NONE.

Board of Governors of the Federal Reserve System, November 1, 2021.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2021–24159 Filed 11–4–21; 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 November 22, 2021.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Sherrian M. Logan, the Dana M. Peoples Revocable Trust No. 1, Dana Peoples, as trustee; the Ann Elizabeth Murphy Family Trust, Jeffrey Collins Davis, Jr., individually and as trustee; and the Jeffrey C. Davis, Jr., Family Trust, all of Winfield, Alabama, Ann Elizabeth Murphy, individually and as trustee, Memphis, Tennessee;* as a group acting in concert, to retain voting shares of Peoples Bancorporation, Inc., and thereby indirectly retain voting shares of State Bank & Trust, both of Winfield, Alabama.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–24276 Filed 11–4–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Amended Order Implementing Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID–19 Pandemic

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of agency amended order.

SUMMARY: On October 25, 2021, the President issued a Proclamation, ''*Advancing the Safe Resumption of Global Travel During the COVID–19 Pandemic.*'' Pursuant to this Proclamation, the President has implemented a global suspension and restriction on entry for noncitizens who are nonimmigrants seeking to enter the United States by air travel and who are not fully vaccinated against COVID–19. The Proclamation directs the Secretary of Health and Human Services (HHS), through the Director of the Centers for Disease Control and Prevention (CDC), to implement the Proclamation as it applies to public health. As such, CDC announces an Amended Order implementing the Proclamation requiring noncitizens who are nonimmigrants seeking to enter the United States by air travel to provide proof of being fully vaccinated against COVID–19 prior to boarding an aircraft to fly to the United States, with only limited exceptions in accordance with the Proclamation. This Amended Order was signed by the CDC Director on October 30, 2021, and supersedes the previous Order signed by the CDC Director on October 25, 2021.

DATES: This Amended Order will become effective at 12:01 a.m. EST on November 8, 2021.

FOR FURTHER INFORMATION CONTACT: Jennifer Buigut, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329. Telephone: 404–498–1600. Email: *dgmqpolicyoffice@cdc.gov.*

SUPPLEMENTARY INFORMATION: The President implemented a global suspension and restriction on entry for noncitizens who are nonimmigrants seeking to enter the United States by air travel and who are not fully vaccinated against COVID–19, with only limited exceptions. The Proclamation does not apply to crew members of airlines or other aircraft operators if they follow industry standard protocols for the prevention of COVID–19.

In accordance with the Proclamation and CDC's Amended Order, *Covered Individuals* (noncitizens who are nonimmigrants, excluding air crew) seeking to enter the United States by air travel and who are not fully vaccinated against COVID–19 may board an aircraft destined for the United States only if they qualify as *Excepted Covered Individuals.* Noncitizens who are nonimmigrants, excluding air crew, must also provide the airline or aircraft operator with a *Covered Individual Attestation.*

A copy of the Amended Order and Attestation Form is below. A copy of these documents and Technical Instructions can be found at: *https://www.cdc.gov/quarantine/order-safe-travel.html.*

Centers for Disease Control and Prevention (CDC)

Department of Health and Human Services (HHS)

Amended Order Implementing Presidential Proclamation on Advancing the Safe Resumption Of Global Travel During the Covid–19 Pandemic

SUMMARY

On October 25, 2021, the President issued a Proclamation pursuant to Sections 1182(f) and 1185(a)(1) of Title 8, and Section 301 of Title 3, United States Code, (the ''Proclamation''), titled, ''*Advancing the Safe Resumption of Global Travel During the COVID–19 Pandemic.*'' Pursuant to this Proclamation, the President has implemented a global suspension and restriction on entry for noncitizens who are nonimmigrants seeking to enter the United States by air travel and who are not fully vaccinated against COVID–19. The Proclamation directs the Secretary of Health and Human Services (HHS), through the Director of the Centers for Disease Control and Prevention (CDC), to implement the Proclamation as it applies to public health in accordance with appropriate public health protocols and consistent with CDC's independent public health judgment. This Order and accompanying Technical Instructions implement the President's direction.

The Proclamation does not alter the obligation of persons, including persons whose entry is not covered by the Proclamation, to comply with the applicable requirements of CDC Orders, including:

- *Requirement for Proof of Negative COVID–19 Test or Recovery from COVID–19 for All Air Passengers Arriving in the United States* (published at 86 FR 7387, January 28, 2021) (as may be further amended);
- *Requirement for Persons to Wear Masks While on Conveyances and at Transportation Hubs* (published at 86 FR 8025, February 3, 2021) (as may be further amended); and
- Other CDC Orders that may be published relating to preventing the introduction, transmission, and spread of COVID–19 into and throughout the United States.

This Amended Order supersedes the previous Order signed by the CDC Director on October 25, 2021, implementing the President's direction. This Order shall enter into effect at 12:01 a.m. EST (5:01 a.m. GMT) on November 8, 2021.

Definitions

Accepted COVID–19 Vaccine means:

- A vaccine authorized for emergency use or approved by the U.S. Food and Drug Administration; [1] or
- A vaccine listed for emergency use (EUL) by the World Health Organization (WHO); [2] or
- A vaccine or combination of vaccines [3] listed by CDC in Technical Instructions to this Order.

Covered Individual means any passenger covered by the Proclamation and this Order: A noncitizen [4] who is a nonimmigrant seeking to enter the United States by air travel. This term does not apply to crew members of airlines or other aircraft operators if such crewmembers and operators adhere to all industry standard protocols for the prevention of COVID–19, as set forth in relevant guidance for crewmember health issued by the CDC

[1] For a list of vaccines approved or authorized in the United States to prevent COVID–19, see *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html*

[2] See WHO's website for more information about WHO-listed COVID–19 vaccines.

[3] CDC has not recommended the use of heterologous (*i.e.,* ''mix-and-match'') primary series. However, the use of such strategies (including mixing of mRNA, adenoviral, and mRNA plus adenoviral products) is increasingly common in many countries outside of the United States. Accordingly, additional vaccinations or combinations of vaccinations may be listed in CDC's Technical Instructions to this Order for purposes of the interpretation of vaccination records.

[4] For purposes of the Order, U.S. lawful permanent residents and U.S. nationals will be treated in the same manner as U.S. citizens.

or by the Federal Aviation Administration in coordination with the CDC.

Excepted Covered Individual means a *Covered Individual* who is not fully vaccinated against COVID–19 and meets the criteria for an exception under the Proclamation and this Order.

Covered Individual Attestation means the attestation in Attachment A, [5] in written or electronic form, that must be completed by each *Covered Individual* who is permitted to enter the United States under the Proclamation and this Order.

Foreign country means anywhere that is not a state, territory, or possession of the United States.

Foreign Country with Limited COVID–19 Vaccine Availability means a foreign country where less than 10 percent of the country's total population has been fully vaccinated with any available COVID–19 vaccine. These countries are listed by CDC in Technical Instructions.

Fully Vaccinated Against COVID–19 means it has been:

- 2 weeks (14 days) or more since a person received one dose of an accepted single-dose-series COVID–19 vaccine; OR
- 2 weeks (14 days) or more since a person's second dose in a 2-dose series of an accepted COVID–19 vaccine; OR
- 2 weeks (14 days) or more since a person received the full series of an ''active'' (not placebo) COVID–19 vaccine in the U.S.-based AstraZeneca or Novavax COVID–19 vaccine trials; OR
- 2 weeks (14 days) or more since the person received a complete series of a vaccine or combination of vaccines listed by CDC in Technical Instructions.

Not Fully Vaccinated Against COVID–19 means a person does not meet the definition of *Fully Vaccinated Against COVID–19.*

Proof of Being Fully Vaccinated Against COVID–19 means a paper or digital format of a vaccination record or a verifiable vaccination record, as listed by CDC in Technical Instructions, confirming that the person is *Fully Vaccinated Against COVID–19.*

Self-isolation means, for purposes of this Order, actions taken by an *Excepted Covered Individual* who tests positive on a viral test for COVID–19 administered on a specimen collected 3–5 days after arriving in the United States or develops COVID–19 symptoms. These actions include:

- separating from other individuals, staying in a home or other residence for at least 10 days after symptom onset and after resolution of fever for at least 24 hours and improvement of other symptoms; or
- separating from other individuals, staying in a home or other residence for 10 days after the first positive test if asymptomatic;

AND

- observing other public health precautions as set forth in CDC guidance.[6]

Self-quarantine means, for purposes of this Order, actions taken by an *Excepted Covered Individual* to separate from other individuals after arriving in the United States, including staying in a home or other residence for a full 7 days and observing public health precautions as set forth in CDC guidance.[7]

Viral test means a viral detection test for current infection (*i.e.,* a nucleic acid amplification test [NAAT] or a viral antigen test) approved or authorized by the U.S. Food and Drug Administration for the detection of SARS–CoV–2.

United States or *U.S.* has the same definition as ''United States'' in 42 CFR 71.1(b), meaning ''the 50 States, District of Columbia, and the territories (also known as possessions) of the United States, including American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands.''

Background

Since January 2020, the respiratory disease known as ''COVID–19,'' caused by a novel coronavirus (SARS–CoV–2), has spread globally, including cases reported in all 50 states within the United States, plus the District of Columbia and all U.S. territories. As of October 22, 2021, there have been over 242,000,000 million cases of COVID–19 globally, resulting in over 4,900,000 deaths.[8] More than 45,000,000 cases have been identified in the United States, with new cases reported daily, and over 733,000 deaths attributed to the disease.[9] A renewed surge in cases in the United States began in early July 2021; daily case counts rose from 19,000 cases on July 1, 2021 to 159,000 cases on September 1, 2021. While cases are currently decreasing in the United States, during the entirety of this pandemic, cases have tended to surge in waves, including after high-volume travel periods, with four waves as of October 2021.[18] Therefore, additional surges of cases and deaths are very possible.

The United States is taking a multi-layered approach to combatting COVID–19, concurrently preventing and slowing the continued introduction of cases and further spread of the virus within U.S. communities. Vaccination is the most important measure for reducing risk for SARS–CoV–2 transmission and in avoiding severe illness, hospitalization, and death. Studies so far show that vaccinated people are five times less likely to be infected and more than 10 times less likely to experience hospitalization or death than people who are not fully vaccinated against COVID–19.[10]

On October 25, 2021, the President issued a Proclamation under 3 U.S.C. 301 and 8 U.S.C. 1182(f), 1185(a)(1), titled, ''*Advancing the Safe Resumption of Global Travel During the COVID–19 Pandemic.*'' The Proclamation revokes prior, country-specific presidential proclamations issued under these authorities in response to the outbreak of COVID–19. In their place, the President has implemented a global suspension and restriction on entry for noncitizens who are nonimmigrants seeking to enter the United States by air travel and who are not fully vaccinated against COVID–19, with only limited exceptions. This Amended Order and accompanying technical instructions implement the President's Proclamation. As further explained in this Amended Order, CDC will be implementing the Proclamation, among other ways, through a requirement that certain *Excepted Covered Individuals* who are unable to present *Proof of Being Fully Vaccinated Against COVID–19* instead present a *Covered Individual Attestation* to the airline or aircraft operator prior to boarding the aircraft.

[5] CDC encourages airlines and aircraft operators to incorporate the attestation into paperless check-in processes. An airline or aircraft operator may use a third party (including a third-party application) to collect attestations, including to provide translations. However, an airline or aircraft operator will have sole legal responsibility to provide and collect attestations, to ensure the accuracy of any translation, and to comply with all other obligations under agency directives implementing the Proclamation. An airline or aircraft operator is responsible for any failure of a third party to comply with such directives. An airline or aircraft operator may not shift any legal responsibility to a third party.

[6] Quarantine and Isolation, available at *https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html.*

[7] Ibid.

[8] COVID–19 Map—Johns Hopkins Coronavirus Resource Center (jhu.edu).

[9] CDC COVID Data Tracker.

[10] The Possibility of COVID–19 after Vaccination: Breakthrough Infections, *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/why-measure-effectiveness/breakthrough-cases.html.*

Persons Whose Entry Is Not Covered by the Proclamation or Who are Eligible for an Exception to the Requirement To Present Proof of Being Fully Vaccinated Against COVID–19

The Proclamation applies only to non-U.S. citizens seeking entry as nonimmigrants. Individuals seeking entry to the United States as immigrants are subject to the medical examination and vaccination requirements of 8 U.S.C. 1182(a)(1)(A) and 42 CFR part 34. These requirements are further described in CDC's *COVID–19 Technical Instructions for Panel Physicians.*[11]

The Proclamation does not apply to crew members of airlines or other aircraft operators if they follow industry standard protocols for the prevention of COVID–19.[12] Accordingly, per the terms of the Proclamation, these individuals are not *Covered Individuals* and are not required to present *Proof of Being Fully Vaccinated* nor required to present a completed *Covered Individual Attestation* to the airline or aircraft operator before boarding an aircraft destined to the United States.

The Proclamation permits *Excepted Covered Individuals* to enter the United States by air if they meet certain criteria as determined by the CDC. Except where otherwise indicated, these *Excepted Covered Individuals* will be required to present a *Covered Individual Attestation* to the airline or aircraft operator before boarding an aircraft destined to the United States. These categories include:

Diplomatic and Official Foreign Government Travel. The Proclamation excepts any noncitizen seeking entry into or transiting the United States for certain diplomatic or official foreign government activities. This includes:

- Noncitizens traveling pursuant to one of the following nonimmigrant visa classifications: A–1, A–2, C–2, C–3 (as a foreign government official or immediate family member of an official), E–1 (as an employee of TECRO or TECO or the employee's immediate family members), G–1, G–2, G–3, G–4, NATO–1 through NATO–4, or NATO–6 (or seeking to enter as a nonimmigrant in one of those NATO classifications); or
- Any noncitizen whose travel falls within the scope of section 11 of the United Nations Headquarters Agreement or other travel pursuant to a United States legal obligation (as evidenced by a letter of invitation from the United Nations or other documentation showing the purpose of such travel). Such an individual will need to present an official letter, such as a letter from the U.S. government or foreign government to the airline or aircraft operator. If invited by the United Nations, such an individual will need to present to the airline or aircraft operator a letter of invitation from the United Nations or other documentation showing the purpose of such travel.

These persons will be required to provide the *Covered Individual Attestation* to the airline or aircraft operator before boarding an aircraft destined to the United States. Such individuals must also attest to agreeing and arranging to be vaccinated within 60 days of arriving in the United States, or as soon thereafter as is medically appropriate as determined by CDC, if they intend to stay in the United States for more than 60 days and have received no vaccine series. If such an individual has previously received a COVID–19 vaccine that is authorized or approved by the noncitizen's country of nationality but is not an *Accepted COVID–19 Vaccine,* then the individual will not need to agree or arrange to be vaccinated in the United States. In addition, if the CDC Director, in consultation with the Secretary of State, determines that the individual cannot complete the requirements of the *Covered Individual Attestation* consistent with the purposes of their official foreign government activities, then the individual is not required to attest to agreeing and arranging to complete the requirements of the *Covered Individual Attestation.*

Children. The Proclamation excepts noncitizens who are nonimmigrants for whom, given their age, requiring vaccination would be inappropriate, as determined by the CDC, taking into account global vaccine availability for individuals in that age group. In the United States, COVID–19 vaccinations are widely available for adolescents, with a vaccine approved for those 16 years and older and authorized for those 12 to 15 years of age. However, the same availability does not exist globally. Accordingly, considering the difficulty potentially posed to families traveling together when some members of the family can be vaccinated and others cannot, persons under the age of 18 years meet the age-based exception in the Proclamation.

Noncitizens who are nonimmigrants and who are under the age of 18 years and unable to present *Proof of Being Fully Vaccinated Against COVID–19* must present a completed *Covered Individual Attestation* to the airline or aircraft operator prior to embarking an aircraft destined to the United States. However, as part of this attestation, children under the age of 18 will not be required to attest (or have a parent or guardian attest on their behalf) to having arranged to self-quarantine in the United States after arrival. Based on the potential difficulty that self-quarantine may pose to children under 18 years of age especially when accompanied by a vaccinated parent or guardian who is not required to self-quarantine, CDC has determined that self-quarantine should not be required. Nevertheless, children under 18 years of age will be required to attest (or have a parent or guardian attest on their behalf) to arranging to be tested for COVID–19 3–5 days after arrival and to self-isolate if the test result should be positive or if the child develops COVID–19 symptoms. CDC believes that this approach fairly balances the interests of families traveling to the United States with protecting the public's health. CDC guidance strongly recommends vaccination for all eligible children under 18. However, given the still evolving circumstances of vaccination for children, attestation regarding post-arrival vaccination will also not be required for children under 18 at this time. This determination will be periodically reevaluated.

Clinical Trials. The Proclamation excepts noncitizens who are nonimmigrants and who have participated or are participating in certain clinical trials for COVID–19 vaccination, as determined by the CDC. Qualifying vaccine candidates will be specified in CDC's Technical Instructions to this Order. Because these clinical trial participants may have taken a COVID–19 vaccine or series of COVID–19 vaccines that do not meet the definition of an *Accepted COVID–19 Vaccine,* these participants may not be able to present *Proof of Being Fully Vaccinated Against COVID–19.* Accordingly, noncitizens who are nonimmigrants and who have participated or are participating in certain COVID–19 vaccine trials and unable to present *Proof of Being Fully Vaccinated Against COVID–19* must

[11] *https://www.cdc.gov/immigrantrefugeehealth/panel-physicians/covid-19-technical-instructions.html.*

[12] Crew members on official duty assigned by the airline or operator that involves operation of aircraft, or the positioning of crew not operating the aircraft (*i.e.,* on ''deadhead'' status), are exempt from the requirements of the Order provided their assignment is under an air carrier's or operator's occupational health and safety program that follows applicable industry standard protocols for the prevention of COVID–19 as set forth in relevant Safety Alerts for Operators (SAFOs) issued by the Federal Aviation Administration (FAA), *i.e.,* SAFO 20009, COVID–19: Updated Interim Occupational Health and Safety Guidance for Air Carriers and Crews, available at *https://www.faa.gov/other_visit/aviation_industry/airline_operators/airline_safety/safo/all_safos/media/2020/SAFO20009.pdf.* CDC will provide further information in Technical Instructions.

present a completed *Covered Individual Attestation* to the airline or aircraft operator prior to embarking an aircraft destined to the United States. However, CDC has determined that these individuals should not be required to attest to agreeing and arranging to self-quarantine or to be vaccinated after arriving in the United States. Requiring self-quarantine after arrival could potentially discourage clinical trial participants which would not serve the interests of public health and requiring vaccination could potentially invalidate the clinical trial study. Nevertheless, these individuals will be required to attest to arranging to be tested for COVID–19 3–5 days after arrival and to self-isolate if the test result should be positive or if they develop COVID–19 symptoms.

Medical Contraindications. The Proclamation excepts noncitizens who are nonimmigrants for whom receiving an accepted COVID–19 vaccine is medically contraindicated as determined by a licensed physician.[13] Accordingly, individuals with medical contraindications to an accepted COVID–19 vaccine (*e.g.,* a demonstrated anaphylactic reaction to a prior dose of a COVID–19 vaccine or vaccine component), as further described in CDC's Technical Instructions to this Order, are not required to present *Proof of Being Fully Vaccinated Against COVID–19.* COVID–19 vaccinations have been overwhelmingly proven to be safe and effective at preventing severe illness, hospitalizations, and deaths from COVID–19. However, as is the case with any vaccine, certain medical complications can occur, such as a severe allergic reaction. CDC intends for this exception to be applied in strict accordance with scientific evidence and will provide additional details concerning exceptions for medical contraindications in CDC's Technical Instructions to this Order. Persons granted an exception based on medical contraindications will be required to present a *Covered Individual Attestation* to the airline or aircraft operator prior to embarking an aircraft destined to the United States but are not required to attest to agreeing and arranging to be vaccinated after arriving in the United States.

Humanitarian and Emergency Exceptions. The Proclamation excepts any noncitizen nonimmigrant who has been granted an exception by the CDC for humanitarian or emergency reasons, as determined by the CDC. CDC will apply this exception extremely narrowly, such as when an individual must travel to the United States to preserve health and safety (*e.g.,* emergency medical evacuations) and is unable to complete the vaccination requirement before travel. Individuals and organizations sponsoring individuals who fit the exception criteria should contact the U.S. embassy or consulate in or nearest the country from which they are departing for the United States. The embassy will then transmit this information to the CDC for consideration. Any noncitizen who is a nonimmigrant granted an exception for humanitarian or emergency reasons must present an official U.S. government letter and a completed *Covered Individual Attestation* to the airline or aircraft operator prior to embarking an aircraft destined to the United States. Such individual must also attest to agreeing and arranging to be vaccinated within 60 days of arriving in the United States, or as soon thereafter as is medically appropriate as determined by CDC, if they intend to stay in the United States for more than 60 days.

Limited Vaccine Availability. The Proclamation excepts any noncitizen who is a nonimmigrant with a nonimmigrant visa (excluding a B–1 or B–2 visa) and who is a citizen of a *Foreign Country with Limited COVID–19 Vaccine Availability,* which is defined pursuant to the Proclamation and this Order as a foreign country where less than 10 percent of the country's total population has been fully vaccinated with any available COVID–19 vaccine or is otherwise determined by the Director of the CDC to qualify as a country where the availability of COVID–19 vaccination is limited. The list of countries falling below the 10 percent threshold will be maintained by CDC in Technical Instructions to this Order and will be reviewed on a regular basis. In developing and maintaining this list, CDC will rely on official source data as reported by foreign ministries of health but may also rely on other sources such as additional information provided by U.S. embassies and consulates. Currently, 50 countries report having less than 10 percent of their populations fully vaccinated against COVID–19.[14]

Individuals entering the United States under this exception must present a completed *Covered Individual Attestation* to the airline or aircraft operator prior to embarking an aircraft destined to the United States. Additionally, these individuals must attest to agreeing and arranging to be vaccinated within 60 days of arriving in the United States, or as soon thereafter as is medically appropriate as determined by CDC, if they intend to stay in the United States for more than 60 days.

Members of the U.S. Armed Forces. The Proclamation excepts noncitizens who are members of the U.S. Armed Forces and spouses or children of members of the U.S. Armed Forces. CDC intends to apply this exception in a similar manner as in the CDC Order, ''*Requirement for Proof of Negative COVID–19 Test or Recovery from COVID–19 for All Air Passengers Arriving in the United States.*'' U.S. Armed Forces observe U.S. Department of Defense guidance to prevent the transmission of COVID–19 as set forth in Force Protection Guidance Supplement 20—Department of Defense Guidance for Personnel Traveling During the Coronavirus Disease 2019 Pandemic (April 12, 2021). Accordingly, members of the U.S. Armed Forces, and their spouses and children, if traveling with a U.S. military identification document or other proof of status as a member or spouse or child (under 18 years of age) of a member of the U.S. Armed Forces, must attest to their status on the *Covered Individual Attestation,* but will not be required to attest to agreeing and arranging to complete the requirements of the *Covered Individual Attestation.*

Sea Crew Members. The Proclamation excepts any noncitizen seeking entry as a sea crew member traveling pursuant to a C–1 and D nonimmigrant visa, if such crew member adheres to all industry standard protocols for the prevention of COVID–19, as set forth in relevant guidance for crew member health by the CDC.[15] Any passenger granted an exception as a Sea Crew Member must present documentation to the airline from their employer indicating that their entry to the United States is required for the purpose of operating a vessel that will depart from a U.S. seaport. Individuals entering the United States under this exception must present a completed *Covered Individual Attestation* to the airline or aircraft

[13] Objections to vaccination based on religious or moral convictions do not qualify under this or any other exception listed in the Proclamation or this Order.

[14] CDC COVID Data Tracker: Global COVID–19 Vaccination.

[15] See CDC's Technical Instructions for this Order for additional information regarding post-arrival public health management of sea crew. Relevant CDC guidance pertaining to sea crew members serving on board cruise ships has been issued as part of the *Temporary Extension and Modification of the Conditional Sail Order* (available at *https://www.cdc.gov/quarantine/cruise/covid19-cruiseships.html*). Additional guidance applicable to crew serving onboard all vessels is available at *https://www.cdc.gov/quarantine/maritime/recommendations-for-ships.html.*

operator prior to embarking an aircraft destined to the United States. Additionally, these individuals must attest to agreeing and arranging to be vaccinated within 60 days of arriving in the United States, or as soon thereafter as is medically appropriate as determined by CDC, if they intend to stay in the United States for more than 60 days.

National Interest Exception. The Proclamation excepts any noncitizen or group of noncitizens whose entry is in the U.S. national interest, as determined by the Secretary of State, the Secretary of Transportation, or the Secretary of Homeland Security, or their designees. Any *Excepted Covered Individual* granted an exception in the national interest must present an official U.S. government letter and a completed *Covered Individual Attestation* to the airline or aircraft operator prior to embarking an aircraft destined to the United States. Such an individual must also attest to agreeing and arranging to be vaccinated within 60 days of arriving in the United States, or as soon thereafter as is medically appropriate, if they intend to stay in the United States for more than 60 days.

Requirement To Provide an Covered Individual Attestation for an Excepted Covered Individual Who Is Unable To Present Proof of Being Fully Vaccinated

Covered Individuals seeking to enter the United States by air travel and who are not *Fully Vaccinated Against COVID–19* may embark an aircraft destined for the United States only if they qualify as *Excepted Covered Individuals* pursuant to the Proclamation. Under the Proclamation, such individuals must agree that they will comply with applicable public health precautions established by CDC to protect against the public health risk posed by these travelers entering into the United States. These include:

- Providing proof in the form of an attestation of pre-departure testing for COVID–19, as determined by the CDC;
- taking precautions during air travel to protect against the further introduction, transmission, and spread of COVID–19, including by complying with the requirement to wear a face mask, as determined by the CDC;
- providing proof in the form of an attestation of having arranged for post-arrival testing for COVID–19, as determined by the CDC; and
- providing proof in the form of an attestation of having arranged to self-quarantine or self-isolate after arriving in the United States, as determined by the CDC.

Some categories of *Excepted Covered Individuals* (subject to certain exceptions) must agree to become fully vaccinated against COVID–19 within 60 days [16] of arriving in the United States if the individual intends to stay in the United States for more than 60 days, or as soon thereafter as is medically appropriate as determined by the CDC, and must provide proof in the form of an attestation of having agreed and arranged to become fully vaccinated against COVID–19 after arriving in the United States.

The Proclamation directs the HHS Secretary, acting through the CDC Director, to implement the Proclamation as it applies to public health consistent with CDC's independent public health judgment. In accordance with the President's direction, this Amended Order requires that, to travel to the United States by air travel, an *Excepted Covered Individual* who is unable to present *Proof of Being Fully Vaccinated Against COVID–19* must present a *Covered Individual Attestation* to the airline or aircraft operator prior to embarking the aircraft.

The *Covered Individual Attestation* must be completed, in written or electronic form, by the *Excepted Covered Individual* and is subject to 18 U.S.C. 1001. As further explained in the attached Attestation form (Attachment A), persons who knowingly submit false information may be subject to fines, imprisonment, and other penalties. Airlines or other aircraft operators, as directed by the Transportation Security Administration (TSA), including through a forthcoming Security Directive to be issued after consultation with CDC, and consistent with this Amended Order, will be required to retain a copy of the *Covered Individual Attestation* for 2 years; however, individuals are not required to retain a copy of the attestation in their possession upon arriving in the United States.

Future CDC orders implementing the Proclamation may require other public health measures consistent with the Proclamation to protect against the further introduction, transmission, and spread of COVID–19 into the United States by *Covered Individuals.*

This Amended Order clarifies certain ambiguity that existed at the time of the issuance of the Order on October 25, 2021, regarding the requirement for post-arrival quarantine for children under 18 years of age and participants in certain COVID–19 clinical trials. This Amended Order clarifies that such individuals are not required to attest to having to agree and arrange to self-quarantine after arriving in the United States. Therefore, to the extent that this ambiguity would have caused these individuals to self-quarantine, this ambiguity is now clarified and accordingly relieves these individuals of what may have otherwise been perceived as an obligation. It is imperative that these amendments be issued without delay so that these individuals may have the necessary clarity to arrange their travel plans in accordance with the requirements of this Amended Order.

This Amended Order is not a rule within the meaning of the Administrative Procedure Act (''APA'') but rather an Order implementing the President's Proclamation, which itself is not subject to the APA. Additionally, considering the President's Proclamation is effective on November 8, 2021, it is imperative that CDC issue this Amended Order without delay. If this Amended Order qualifies as a new rule under the APA, notice and comment and a delay in effective date are not required because there is good cause to dispense with prior public notice and comment and a delay in effective date. *See* 5 U.S.C. 553(b)(B), (d)(3).

Considering the rapid and unpredictable developments in the public health emergency caused by COVID–19, it would be impracticable and contrary to the public's health, and by extension the public's interest, to delay the issuance and effective date of this Amended Order implementing the President's Proclamation. Further delay could increase risk of transmission and importation of additional undetected cases of SARS–CoV–2 Delta variant or other emerging variants through not fully vaccinated passengers.

This Amended Order is also an economically significant regulatory action under Executive Order 12866 and has therefore been reviewed by the Office of Information and Regulatory Affairs of the Office of Management and Budget. Similarly, the Office of Information and Regulatory Affairs has determined that if this Order were a rule, it would be a major rule under Subtitle E of the Small Business

[16] CDC concurs that 60 days is the appropriate time frame for requiring that persons arriving in the United States be fully vaccinated against COVID–19. The mRNA COVID–19 vaccines (Pfizer-BioNTech and Moderna) available in the United States are administered 3–4 weeks apart (see *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html*). It takes 14 days after the 2nd dose to be considered fully vaccinated. Therefore, it is reasonable to conclude that individuals should be able to complete the vaccination series and the 14-day period within 60 days of arriving in the United States.

Regulatory Enforcement Fairness Act of 1996 (the Congressional Review Act), 5 U.S.C. 804(2), but there would not be a delay in its effective date as the agency has determined that there would be good cause to make the requirements herein effective immediately under the APA, 5 U.S.C. 808(2).

If any provision of this Amended Order implementing the President's Proclamation, or the application of any provision to any carriers, persons, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any carriers, persons, or circumstances other than those to which it is held invalid, shall remain valid and in effect.

Pursuant to 5 U.S.C. 553(b)(B), and for the reasons stated above, I hereby conclude that notice-and-comment rulemaking would defeat the purpose of this Amended Order implementing the President's Proclamation and endanger the public health, and is, therefore, impracticable and contrary to the public interest. For the same reasons, I have determined, consistent with 5 U.S.C. 553(d)(3), that there is good cause to make this Amended Order implementing the President's Proclamation effective without a 30-day delay in effective date.

Action

Accordingly, for the reasons set forth in the Proclamation and in this Order:

1. Directions to Airlines & Other Aircraft Operators

As directed by TSA, including through a forthcoming Security Directive to be issued after consultation with CDC, and consistent with this Order, any airline or other aircraft operator transporting by air into the United States individuals who are *Covered Individuals* from any foreign country, as determined and confirmed by the airline or other aircraft operator, will be required to:

A. Confirm that every *Covered Individual,* unless excepted, prior to boarding the aircraft, has presented paper or digital documentation of *Proof of Being Fully Vaccinated Against COVID–19* that includes personal identifiers (*e.g.,* name and date of birth) that matches the personal identifiers on the passenger's passport or other travel documents, and provides a *Covered Individual Attestation.*

B. Confirm that every *Covered Individual* who has not presented *Proof of Being Fully Vaccinated Against COVID–19* prior to boarding the aircraft, has presented documentation proving that they are an *Excepted Covered Individual* under the Proclamation and this Order as further explained by CDC in Technical Instructions for this Order.

C. Confirm that every *Excepted Covered Individual* who has not presented *Proof of Being Fully Vaccinated Against COVID–19,* prior to boarding the aircraft, provides a *Covered Individual Attestation,* as applicable and as further explained in CDC Technical Instructions to this Order, attesting to the following:

a. Being excepted from the requirement to present *Proof of Being Fully Vaccinated Against COVID–19* for one of the reasons set forth in the Proclamation and this Order;

b. having arranged to be tested with a COVID–19 viral test 3–5 days after arriving in the United States, unless the *Excepted Covered Individual* has documentation of having recovered from COVID–19 in the past 90 days;

c. having arranged to self-quarantine, even if the test result to the post-arrival viral test is negative, unless the *Excepted Covered Individual* has documentation of having recovered from COVID–19 in the past 90 days; and

d. having arranged to self-isolate if the result of the post-arrival viral test is positive or if they develop COVID–19 symptoms.

D. Confirm that every *Excepted Covered Individual* who does not present *Proof of Being Fully Vaccinated Against COVID–19,* provides a *Covered Individual Attestation,* as applicable and as further explained in CDC Technical Instructions to this Order, attesting to the following:

a. Agreeing to be vaccinated and having arranged to become fully vaccinated against COVID–19 within 60 days after arriving in the United States, or as soon thereafter as is medically appropriate as determined by CDC, if such person intends to stay in the United States for more than 60 days, unless the individual is excepted from this requirement.

E. Not board any *Covered Individual* without confirming the documentation as set forth in A, B, C, or D of this section.

The attestation is attached to this order as Attachment A.[17]

2. Requirements for Aircraft Passengers

In addition, I order that any aircraft passenger[18] who is a *Covered Individual* under the Proclamation, prior to boarding an aircraft traveling from a foreign country to the United States, shall—

A. Present to the airline or other aircraft operator a paper or digital documentation reflecting *Proof of Being Fully Vaccinated Against COVID–19* and provides a *Covered Individual Attestation.*

OR

B. If not presenting *Proof of Being Fully Vaccinated Against COVID–19,* present to the airline or aircraft operator documentation confirming that they are an *Excepted Covered Individual* under the Proclamation and this Order, as applicable and as further explained by CDC in Technical Instructions for this Order.

C. If an *Excepted Covered Individual,* accurately complete and provide the airline or aircraft operator with a *Covered Individual Attestation,* as applicable and as further explained by CDC in Technical Instructions for this Order, attesting that the *Excepted Covered Individual:*

a. Is excepted from the requirement to present *Proof of Being Fully Vaccinated Against COVID–19* for one of the reasons set forth in the Proclamation and this Order;

b. agrees and has arranged to be tested with a COVID–19 viral test 3–5 days after arriving in the United States, unless the *Excepted Covered Individual* has documentation of having recovered from COVID–19 in the past 90 days;

c. agrees and has arranged to self-quarantine, even if the test result to the post-arrival viral test is negative, unless the *Excepted Covered Individual* has documentation of having recovered from COVID–19 in the past 90 days; and

d. agrees and has arranged to self-isolate if the result of the post-arrival viral test is positive or if they develop COVID–19 symptoms.

D. If an *Excepted Covered Individual,* provide the airline or aircraft operator with a *Covered Individual Attestation,* as applicable and as further explained by CDC in Technical Instructions for this Order, additionally attesting that the *Excepted Covered Individual:*

(1) Agrees to be vaccinated and has arranged to become fully vaccinated against COVID–19 within 60 days after

[17] CDC has provided a combined passenger disclosure and attestation that fulfills the requirements of CDC Orders: *Requirement for Proof of Negative COVID–19 Test Result or Recovery from COVID–19 for All Airline Passengers Arriving into the United States* and *Order Implementing Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID–19 Pandemic.*

[18] A parent or other authorized individual may present the required documentation on behalf of a passenger under 18 years of age. An authorized individual may act on behalf of any passenger who is unable to act on their own behalf (*e.g.,* by reason of age, or physical or mental impairment).

arriving in the United States, or as soon thereafter as is medically appropriate as determined by CDC, if intending to stay in the United States for more than 60 days, unless the individual is excepted from this requirement.

E. Retain a copy of the applicable documentation listed in parts A, B, C, and D of this section and produce such documentation upon request, or as required by, any U.S. government official or a cooperating state, local, territorial, or tribal public health authority after arrival in the United States.

Willfully giving false or misleading information to the government may result in criminal penalties under, *inter alia,* 18 U.S.C. 1001.

This Order shall be enforced through the relevant provisions of law, in coordination with other federal departments and agencies, including the U.S. Department of Justice, U.S. Department of Homeland Security, U.S. Department of State, and U.S. Department of Transportation.

Effective Date

This Order shall enter into effect at 12:01 a.m. EST (5:01 a.m. GMT) on November 8, 2021.

BILLING CODE 4163–18–P

Form OMB Control No: XXXX-XXXX

Expiration date: XX/XX/XXXX[19]

ATTACHMENT A: COMBINED PASSENGER DISCLOSURE AND ATTESTATION TO THE UNITED STATES OF AMERICA

This combined passenger disclosure and attestation fulfills the requirements of U.S. Centers for Disease Control and Prevention (CDC) Orders: *Requirement for Proof of Negative COVID-19 Test Result or Recovery from COVID-19 for All Airline Passengers Arriving into the United States* and *Order Implementing Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID-19 Pandemic.*[20]

[19] Public reporting burden of this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. 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. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA XXXX-XXXX

[20] These requirements (e.g. proof of negative COVID-10 test result and proof of being fully vaccinated against COVID-19)do not apply to crew members of airlines or other aircraft operators if they are traveling for the purpose of operating the aircraft, or repositioning (i.e., on "deadhead" status), provided their assignment is under an air carrier's or operator's occupational health and safety program that follows applicable industry standard protocols for the prevention of COVID-19 as set forth in relevant Safety Alerts for Operators (SAFOs) issued by the Federal Aviation Administration (FAA).

As directed by the CDC and the Transportation Security Administration (TSA), including through a forthcoming Security Directive, to be issued after consultation with CDC, and consistent with CDC's Order implementing the Presidential Proclamation, all airline or other aircraft operators must provide the following disclosures to all passengers prior to their boarding a flight from a foreign country to the United States.

The information provided below must be accurate and complete to the best of the individual's knowledge. Under United States federal law, each passenger must complete the applicable portion of the attestation and provide it to the airline or aircraft operator prior to boarding a flight to the United States from a foreign country. Failure to complete and present the applicable portion of the attestation or submitting false or misleading information, could result in delay of travel, denial of boarding, denial of boarding on future travel, or put the passenger or other individuals at risk of harm, including serious bodily injury or death. Any passenger who fails to comply with these requirements may be subject to criminal penalties. Willfully providing false or misleading information may lead to criminal fines and imprisonment under, among others, 18 U.S.C. § 1001. Providing this information can help protect you, your friends and family,

your communities, and the United States. CDC appreciates your cooperation.

AIRLINE AND AIRCRAFT OPERATOR DISCLOSURE REQUIREMENTS:

As required by United States federal law, all airlines or other aircraft operators must collect the passenger attestation on behalf of the U.S. Government.

All airlines and other aircraft operators must additionally confirm one of the following for each passenger – 2 years and older--prior to their boarding a flight to the United States from a foreign country:

1. A negative result for a *Qualifying Test for Fully Vaccinated* for those passengers who provide proof of being fully vaccinated,
2. A negative result for a *Qualifying Test for Not Fully Vaccinated*, or
3. Documentation of recovery from COVID-19 in the form of a positive COVID-19 viral test on a sample taken no more than 90 days prior to departure and clearance to travel.

As directed by the TSA, including through a forthcoming security directive, all airlines and other aircraft operators must additionally confirm one of the following for each

noncitizen who is a nonimmigrant passenger prior to their boarding a flight to the United States from a foreign country:

1. Proof of being *Fully Vaccinated Against COVID-19*
2. Proof of being excepted from the requirement to be *Fully Vaccinated Against COVID-19*.

SECTION 1:

Passenger Attestation Requirement Relating to Proof of Negative COVID-19 Test Result or Recovery from COVID-19

TO BE COMPLETED BY ALL PASSENGERS:

1. [ ] I attest that I am fully vaccinated against COVID-19 and have received a **negative** pre-departure test result for COVID-19. The test was a viral test that was conducted on a specimen collected from me no more than **3 days** before this flight's departure.

   [ ] On behalf of [_____], I attest that this person is fully vaccinated against COVID-19 and received a **negative** pre-departure test result for COVID-19. The test was a viral test that was conducted on a specimen collected from the person no more than **3 days** before the flight's departure.

2. [ ] I attest that I am **not** fully vaccinated against COVID-19 and have received a **negative** pre-departure test result for COVID-19. The test was a viral test that was conducted

on a specimen collected from me no more than **1 day** before the flight's departure.

[ ] On behalf of [_____], I attest that this person is **not** fully vaccinated against COVID-19 and has received a **negative** pre-departure test result for COVID-19. The test was a viral test that was conducted on a specimen collected from the person no more than **1 day** before the flight's departure.

3. [ ] I attest that I tested positive for COVID-19 and **have been cleared for travel** by a licensed healthcare provider or public health official. The test was a viral test that was conducted on a specimen collected from me no more than 90 days before the flight's departure.

[ ] On behalf of [_____], I attest that this person tested positive for COVID-19 and **has been cleared for travel** by a licensed healthcare provider or public health official. The test was a viral test that was conducted on a specimen collected from the person no more than 90 days before the flight's departure.

4. [ ] On behalf of [_____], I attest that this person is between 2 and 17 years of age, is not fully vaccinated against COVID-19, and received a **negative** pre-

departure test result for COVID-19. The test was a viral test that was conducted on a specimen collected from the person no more than **3 days** before the flight's departure and this person is traveling with a fully vaccinated parent(s) or guardian(s).

5. [ ] I attest that I have received a humanitarian or emergency exemption to the testing requirement or the documentation of recovery, as determined by CDC and documented by an official U.S. Government letter.

[ ] On behalf of [_____], I attest that this person has received a humanitarian or emergency exemption to the testing requirement or the documentation of recovery, as determined by CDC and documented by an official U.S. Government letter.

SECTION 2:

Passenger Attestation Requirement Relating to Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID-19 Pandemic

TO BE COMPLETED BY EVERY COVERED INDIVIDUAL:[21]

1. [ ] I attest that I am **fully vaccinated** against COVID-19 (*sign the form to complete the Attestation*).

   [ ] On behalf of [_____], I attest that this person is fully vaccinated against COVID-19 (*sign the form to complete the Attestation*).

2. [ ] I am **not fully vaccinated** and attest that I am **excepted** from the requirement to present *Proof of Being Fully Vaccinated Against COVID-19* based on one of the following *(check only one box, as applicable)*:

   ☐ Diplomatic and Official Foreign Government Travel (*complete sections 3 and 5, unless as determined by CDC, these requirements cannot be completed consistent with the purposes of the official government travel, and sign the form to complete the Attestation*).

[21] This means any passenger covered by the Proclamation and this Order: a noncitizen (other than a U.S. lawful permanent resident or U.S. national) who is a nonimmigrant seeking to enter the United States by air travel. This term does not apply to crew members of airlines or other aircraft operators if such crewmembers and operators adhere to all industry standard protocols for the prevention of COVID-19, as set forth in relevant guidance for crewmember health issued by the CDC or by the Federal Aviation Administration in coordination with the CDC.

- ☐ Child under 18 years of age (*complete section 4 and sign the form to complete the Attestation OR have parent/legal guardian complete section 4 and sign on behalf of a person under 18 years of age*).
- ☐ Participant in certain COVID-19 vaccine trials as determined by CDC (*complete section 4 and sign the form to complete the Attestation*).
- ☐ Medical contraindication to an accepted COVID-19 vaccine as determined by CDC (*complete section 3 and sign the form below to complete the Attestation*).
- ☐ Humanitarian or emergency exception as determined by CDC and documented by an official U.S. Government letter (*complete sections 3 and 5 below and sign the form to complete the Attestation*).
- ☐ Valid nonimmigrant visa holder (excluding B-1 or B-2 visas) and citizen of a *Foreign Country with Limited COVID-19 Vaccine Availability* as determined by CDC (*complete sections 3 and 5 below and sign the form to complete the Attestation*).
- ☐ Member of the U.S. Armed Forces or spouse or child (under 18 years of age) of a member of the U.S. Armed Forces (*sign the form to complete the Attestation*).
- ☐ Sea crew member traveling pursuant to a C-1 and D nonimmigrant visa (*complete sections 3 and 5 below and sign the form to complete the Attestation*).

☐ Person whose entry is in the U.S. national interest as determined by the Secretary of State, the Secretary of Transportation, the Secretary of Homeland Security, or their designees (*complete sections 3 and 5 below and sign the form to complete the Attestation).*

[ ] On behalf of [_____], I attest that this person is **excepted** from the requirement to present *Proof of Being Fully Vaccinated Against COVID-19* based on one of the following *(check only one box, as applicable)*:

☐ Diplomatic and Official Foreign Government Travel (*complete sections 3 and 5, unless as determined by CDC, these requirements cannot be completed consistent with the purposes of the official government travel, and sign the form to complete the Attestation*).

☐ Child under 18 years of age (*complete section 4 and sign the form to complete the Attestation).*

☐ Participant in certain COVID-19 vaccine trials as determined by CDC (*complete section 4 and sign the form to complete the Attestation).*

☐ Medical contraindication to an accepted COVID-19 vaccine as determined by CDC (*complete section 3 and sign the form below to complete the Attestation).*

☐ Humanitarian and emergency exception as determined by CDC and documented by an official U.S. Government letter

(*complete sections 3 and 5 below and sign the form to complete the Attestation*).

☐ Valid nonimmigrant visa holder (excluding B-1 or B-2 visas) and citizen of a *Foreign Country with Limited COVID–19 Vaccine Availability* as determined by CDC (*complete sections 3 and 5 below and sign the form to complete the Attestation*).

☐ Member of the U.S. Armed Forces or spouse or child (under 18 years of age) of a member of the U.S. Armed Forces (*sign the form to complete the Attestation*).

☐ Sea crew member traveling pursuant to a C–1 and D nonimmigrant visa (*complete sections 3 and 5 below and sign the form to complete the Attestation*).

☐ Person whose entry is in the U.S. national interest as determined by the Secretary of State, the Secretary of Transportation, the Secretary of Homeland Security, or their designees (*complete sections 3 and 5 below and sign the form to complete the Attestation*).

3. [ ] I attest that I have made the following arrangements (*must check all boxes*).

☐ To be tested with a COVID-19 viral test 3-5 days after arriving in the United States, unless I have documentation of having recovered from COVID-19 in the past 90 days;

- ☐ To self-quarantine for a full 7 days, even if the test result to my post-arrival viral test is negative, unless I have documentation of having recovered from COVID-19 in the past 90 days; and
- ☐ To self-isolate if the result of the post-arrival viral test is positive or if I develop COVID-19 symptoms.

[ ] On behalf of [_____], I attest that such person is **excepted** from the requirement to present *Proof of Being Fully Vaccinated Against COVID-19* and has made or has had the following arrangements made on their behalf (*must check all boxes*).

- ☐ Testing with a COVID-19 viral test 3-5 days after arriving in the United States, unless such person has documentation of having recovered from COVID-19 in the past 90 days;
- ☐ Self-quarantine for a full 7 days, even if the test result to the person's post-arrival viral test is negative, unless such person has documentation of having recovered from COVID-19 in the past 90 days; and
- ☐ Self-isolation if the result of the person's post-arrival viral test is positive or if the person develops COVID-19 symptoms.

4. [ ] I attest that I have made the following arrangements (*must check all boxes*).

☐ To be tested with a COVID-19 viral test 3-5 days after arriving in the United States, unless I have documentation of having recovered from COVID-19 in the past 90 days; and

☐ To self-isolate if the result of the post-arrival viral test is positive or if I develop COVID-19 symptoms.

[ ] On behalf of [_____], I attest that such person is **excepted** from the requirement to present *Proof of Being Fully Vaccinated Against COVID-19* and has made or has had the following arrangements made on their behalf (*must check all boxes*).

☐ Testing with a COVID-19 viral test 3-5 days after arriving in the United States, unless such person has documentation of having recovered from COVID-19 in the past 90 days; and

☐ Self-isolation if the result of the person's post-arrival viral test is positive or if the person develops COVID-19 symptoms.

5. Do you, or the person you are attesting on behalf of, intend to stay in the United States for more than 60 days?

☐ YES (*complete statement below and then sign form*)

☐ NO *(skip statement below and sign form)*

[ ] If YES, I attest that I agree to be vaccinated and have arranged to become fully vaccinated against COVID-19 within 60 days of arriving in the United States, or as soon thereafter as is medically appropriate.

[ ] If YES, on behalf of [_____], I attest that such person agrees to be vaccinated and has arranged to become fully vaccinated against COVID-19 within 60 days of arriving in the United States, or as soon as thereafter as is medically appropriate.

_____ Print Name

_____ Signature

_____Date

Privacy Act Statement for Travelers Relating to the Requirement to Provide Proof of a Negative COVID-19 Test Result

The United States Centers for Disease Control and Prevention (CDC) requires airlines and other aircraft operators to collect this information pursuant to 42 C.F.R. §§ 71.20 and 71.31(b), as authorized by 42 U.S.C. § 264. Providing this information is mandatory for all passengers arriving by aircraft into the United States. Failure to provide this information may prevent you from boarding the plane. Additionally, passengers will be required to attest to providing complete and accurate information, and failure to do so may lead to other consequences, including criminal penalties. CDC will use this information to help prevent the introduction, transmission, and spread of communicable diseases by performing contact tracing investigations and notifying exposed individuals and public health authorities; and for health education, treatment, prophylaxis, or other appropriate public health interventions, including the implementation of travel restrictions.

The Privacy Act of 1974, 5 U.S.C. § 552a, governs the collection and use of this information. The information maintained by CDC will be covered by CDC's System of Records No. 09-20-0171, Quarantine- and Traveler-Related Activities,

Including Records for Contact Tracing Investigation and Notification under 42 C.F.R. Parts 70 and 71. See 72 Fed. Reg. 70867 (Dec. 13, 2007), as amended by 76 Fed. Reg. 4485 (Jan. 25, 2011) and 83 Fed. Reg. 6591 (Feb. 14, 2018). CDC will only disclose information from the system outside the CDC and the U.S. Department of Health and Human Services as the Privacy Act permits, including in accordance with the routine uses published for this system in the Federal Register, and as authorized by law. Such lawful purposes may include, but are not limited to, sharing identifiable information with state and local public health departments, and other cooperating authorities. CDC and cooperating authorities will retain, use, delete, or otherwise destroy the designated information in accordance with federal law and the System of Records Notice (SORN) set forth above. You may contact the system manager at dgmqpolicyoffice@cdc.gov or by mailing Policy Office, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16-4, Atlanta, GA 30329, if you have questions about CDC's use of your data.

Authority

The authority for the Presidential Proclamation is Sections 1182(f) and 1185(a)(1) of Title 8, and Section 301 of Title 3, United States Code. CDC's Order is issued pursuant to the Presidential Proclamation.

Sherri Berger,

Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2021–24385 Filed 11–3–21; 4:15 pm]

BILLING CODE 4163–18–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Requirement for Airlines and Operators To Collect and Transmit Designated Information for Passengers and Crew Arriving Into the United States; Requirement for Passengers To Provide Designated Information

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of agency order.

SUMMARY: The Centers for Disease Control and Prevention (CDC), a component of the Department of Health and Human Services (HHS), announces the requirement for all airlines and operators to collect and/or maintain passenger and crew contact information (designated information), and for passengers to provide such information to airlines and operators, on flights arriving into the United States. This includes flights with intermediate stops in the United States between the flight's foreign point of origin and the final destination. Unless otherwise transmitted to the U.S. Government via established U.S. Department of Homeland Security (DHS) data systems, airlines and operators are required to retain the designated information for 30 days and transmit it within 24 hours of a request from CDC. Accurate and complete contact information is needed to protect the health of travelers and U.S. communities and for the purposes of public health follow-up.

DATES: This Order is effective beginning 12:01 a.m. Eastern Standard Time on November 8, 2021.

FOR FURTHER INFORMATION CONTACT: Jennifer Buigut, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H16–4, Atlanta, GA 30329. Telephone: 404–498–1600. Email: *dgmqpolicyoffice@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background

The current coronavirus disease 2019 (COVID–19) pandemic has spread globally. As of October 22, 2021, there were over 242,000,000 confirmed cases of COVID–19 globally resulting in over 4,900,000 deaths; more than 45,000,000 cases have been confirmed in the U.S., with new cases being reported daily, and over 733,000 U.S. deaths due to the disease.

In addition, genetic variants of SARS–CoV–2, the virus that causes COVID–19, have been emerging and circulating around the world throughout the pandemic. The Delta variant now makes up over 99% of cases in the United States and is two times as contagious as previous variants. Some of the potential features and consequences of emerging variants are their ability to spread more quickly in people, cause more severe effects in people, evade detection by specific viral diagnostic tests, diminish the efficacy of therapeutic agents such as monoclonal antibodies, and evade natural or vaccine-induced immunity. Preventing the importation and spread of SARS–CoV–2 variants and other communicable diseases of concern requires identifying and contacting travelers who may be infected with, or have been exposed to, communicable diseases.

Air travel may potentially continue the spread of SARS–CoV–2 and its variants as well as other communicable diseases rapidly around the globe, as infected people who may be sick or incubating infection travel to other countries from a country where a disease is spreading. Timely public health follow-up requires health officials to have immediate access to accurate and complete contact information for passengers as they arrive in the United States. Inaccurate or incomplete contact information hampers the ability of public health authorities to protect the health of passengers and the public. The best way to ensure airline passengers' contact information is available in real time is to collect the information before they board a flight. CDC identified the following information as needed for reliable public health management of travelers: full name, address while in the United States, primary contact phone number, secondary or emergency contact phone number, email address, date of birth, airline name, flight number, city of departure, departure date and time, city of arrival, arrival date and time, and seat number.

A copy of the Order is provided below and a copy of the signed Order and Technical Instructions can be found at *https://www.cdc.gov/quarantine/order-collect-contact-info.html.*

Order of the Centers for Disease Control and Prevention, Department of Health and Human Services

Requirement for Airlines and Operators To Collect and Transmit Designated Information for Passengers and Crew Arriving Into the United States; Requirement for Passengers To Provide Designated Information Under 42 CFR 71.4, 71.20, 71.31, and 71.32 as Authorized by 42 U.S.C. 264 and 268

Attention

- All airlines and operators conducting any passenger-carrying operations into the United States from a foreign last point of departure.
- All passengers and crewmembers flying into, or transiting through, the United States from a foreign last point of departure.

Introduction

The Director of the Centers for Disease Control and Prevention (CDC) (Director) is issuing this Order (Order) to require all airlines and operators of flights arriving into the United States from a foreign last point of departure to collect and/or maintain passenger and crewmember contact information (''designated information''). These requirements also apply to flights with intermediate stops in the United States between the flight's foreign point of origin and the final destination.

Airlines and operators are required to collect the five data elements from the interim final rule (IFR) [1] published on February 12, 2020, from passengers, to the extent they exist, and to maintain additional data elements outlined in 42 CFR 71.4(b) [2]—to the extent that such data are already available and maintained by the airline. The data elements from the IFR and the additional data elements outlined in 42 CFR 71.4(b) make up the designated information referred to in this Order. The designated information consists of full name, address while in the United States, primary contact phone number, secondary or emergency contact phone number, email address, date of birth, airline name, flight number, city of departure, departure date and time, city of arrival, arrival date and time, and seat number. Airlines and operators are

[1] *https://www.federalregister.gov/documents/2020/02/12/2020-02731/control-of-communicable-diseases-foreign-quarantine.*

[2] *https://www.ecfr.gov/current/title-42/chapter-I/subchapter-F/part-71#p-71.4(b).*

required to maintain the designated information for crewmembers.

These data elements are necessary for identifying and locating passengers and crewmembers who may have coronavirus disease 2019 (COVID–19) or may have been exposed to a person with COVID–19 or another communicable disease of concern. Unless otherwise transmitted to the U.S. Government via established U.S. Department of Homeland Security (DHS) data systems, airlines and operators are required to retain the designated information for 30 days and transmit it within 24 hours of a request from CDC. The methods of transmission to the U.S. Government, whether transmitted per the CDC technical instructions or whether via an established DHS data system, must be made through approved secure electronic means.

Flights contracted by the U.S. Military services are exempt from this Order. Flights contracted by other federal agencies may also be exempted by CDC on a case-by-case basis. Flights designated as state aircraft under international law (1) by an appropriate United States federal government department or agency, or (2) by a foreign government and granted diplomatic clearance to enter U.S. airspace, are exempt from this Order. All exempt aircraft and persons may voluntarily comply to aid the public health response.

CDC will issue additional operational guidance and technical instructions to airlines and operators regarding the collection, retention, and transmission of the designated information. CDC will maintain and use the designated information called for in this Order in accordance with the Privacy Act of 1974 (5 U.S.C. 552a) and its applicable System of Records Notice.[3]

Background

The current COVID–19 pandemic has spread globally, including cases reported in all 50 States within the United States, the District of Columbia, and U.S. territories. As of October 22, 2021, there have been over 242,000,000 confirmed cases of COVID–19 globally resulting in over 4,900,000 deaths; [4] more than 45,000,000 COVID–19 cases have been confirmed in the United States as well as over 733,000 COVID–19 related deaths, with new cases being reported daily.[5]

In addition, genetic variants of SARS–CoV–2, the virus that causes COVID–19, have been emerging and circulating around the world throughout the COVID–19 pandemic.[6] There is currently one variant of concern (Delta) circulating in the United States and ten other variants being monitored.[7] As of October 22, 2021, the Delta variant made up over 99.0% of new COVID–19 cases in the United States.[8] CDC is closely tracking and reporting variants of SARS–CoV–2 around the world [9] and is working with state and local health departments to establish and expand sequencing capacity to identify, characterize, and report variants.

Some of the potential features and consequences of emerging variants are their ability to spread more quickly in people, cause more severe effects in people, evade detection by specific viral diagnostic tests, diminish the efficacy of therapeutic agents such as monoclonal antibodies, and evade natural or vaccine-induced immunity.[10] The Delta variant spreads faster than other variants and may cause more severe illness in unvaccinated people than previous strains.[11] COVID–19 vaccines protect people against severe illness, including disease caused by the Delta variant and other variants circulating in the United States, decreasing the likelihood of hospitalization or death due to COVID–19. Fully vaccinated people get COVID–19 less often than unvaccinated people; however, people who are infected after being fully vaccinated can be contagious.[12] Preventing the further importation and spread of SARS–CoV–2 variants of concern will require rapid identification and notification of potentially infected or exposed travelers (passengers and crew) so that they and their respective jurisdictional public health officials may take steps to minimize exposure to others.

While vaccination is the most important tool for controlling the pandemic, public health mitigation efforts, including isolation of infected persons and contact tracing and management, remain key to slowing transmission and spread of SARS–CoV–2, even as vaccines are increasingly available in the United States and around the world. Air travel may contribute to the spread of SARS–CoV–2 and other communicable diseases around the globe if people who are infected or incubating infection travel by aircraft, particularly if they fail to use mitigation measures such as masks to prevent COVID–19. Air travel can also increase a person's risk of getting and spreading communicable diseases by bringing people in close contact with others, often for prolonged periods, and exposing them to frequently touched surfaces. While fully vaccinated travelers are less likely to get and transmit SARS–CoV–2, international travel poses additional risks, and even fully vaccinated travelers might be at increased risk for getting and possibly spreading some SARS–CoV–2 variants.[13]

Public health officials may need to follow up with travelers after arrival, either because these travelers may have been exposed before they traveled or because during travel they were possibly exposed to a person known to have a communicable disease that poses a public health threat, such as COVID–19. Other communicable diseases for which CDC conducts contact investigations of exposure while traveling on aircraft are infectious tuberculosis (including multidrug-resistant and extensively drug-resistant infections), measles, pertussis (whooping cough), meningococcal disease, and Middle East Respiratory Syndrome (MERS).[14] [15] [16] [17] Similarly, preventing the further importation and spread of SARS–CoV–2, including variants of concern, requires rapid identification and notification of potentially infected or exposed travelers so that they and their respective jurisdictional public health officials can take steps to minimize exposure to others.

[3] *https://www.cdc.gov/sornotice/09-20-0171.htm.*

[4] *https://covid19.who.int/.*

[5] *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[6] *https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html.*

[7] *https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html.*

[8] *https://covid.cdc.gov/covid-data-tracker/#variant-proportions.*

[9] *https://covid.cdc.gov/covid-data-tracker/#global-variant-report-map.*

[10] *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/scientific-brief-emerging-variants.html.*

[11] *https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html.*

[12] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/why-measure-effectiveness/breakthrough-cases.html.*

[13] *https://www.cdc.gov/coronavirus/2019-ncov/travelers/international-travel-during-covid19.html.*

[14] *https://www.cdc.gov/quarantine/contact-investigation.html.*

[15] Nelson K, Marienau K, Schembri C, Redd S. Measles transmission during air travel, United States, December 1, 2008–December 31, 2011. Travel Med Infect Dis. 2013 Mar–Apr;11(2):81–9. doi: 10.1016/j.tmaid.2013.03.007.

[16] Marienau KJ, Cramer EH, Coleman MS, Marano N, Cetron MS. Flight related tuberculosis contact investigations in the United States: comparative risk and economic analysis of alternate protocols. Travel Med Infect Dis. 2014 Jan–Feb;12(1):54–62. doi: 10.1016/j.tmaid.2013.09.007.

[17] Lippold SA, Objio T, Vonnahme L, et al. Conveyance Contact Investigation for Imported Middle East Respiratory Syndrome Cases, United States, May 2014. Emerg Infect Dis. 2017 Sep;23(9):1585–1589. doi: 10.3201/eid2309.170365.

In the past, public health efforts to follow up with travelers arriving into the United States have been hampered by incomplete or inaccurate contact information, causing delays in conducting contact investigations and requiring resource-intensive entry screening operations to facilitate post-arrival management of travelers.[18] [19] [20] These challenges occurred during the 2014 response to MERS, the 2014–2016 response to the Ebola epidemic in West Africa, and in the early stage of the current COVID–19 public health emergency. Timely public health follow-up requires health officials to have prompt access to accurate and complete contact information for travelers traveling into, or transiting through, the United States. Inaccurate or incomplete contact information decreases the ability of public health authorities to protect the health of travelers and the public. The best way to ensure airline passengers' contact information is available in real time is to collect the information before they board a flight. Given that it is impossible to predict which passengers' or crewmembers' information will be needed for public health purposes, it is necessary to collect information for all passengers and crewmembers originating abroad who intend to travel to, or transit through, the United States. Additionally, many passengers transiting through the United States will likely transit back through the United States on their return trip. If they were exposed during travel, they may return at a time when they are infectious. Facilitating notification to public health authorities at their final destination would prevent potential exposures during such return travel.

CDC identified that the following information is needed for reliable public health management of travelers disembarking in, or transiting through, the United States: Full name, address while in the United States, primary contact phone number, secondary or emergency contact phone number, email address, date of birth, airline name, flight number, city of departure, departure date and time, city of arrival, arrival date and time, and seat number.

CDC's authority for collecting these data elements is contained in 42 CFR 71.4.[21] The first five data elements were added to section 71.4 on February 12, 2020, in response to the current COVID pandemic.[22] Airlines with flights arriving into the United States must collect and, within 24 hours of an order issued by the CDC Director, transmit these five data elements to CDC. The remaining data elements, listed in 42 CFR 71.4(b), are part of CDC's previously existing regulatory scheme. Airlines must also transmit these data elements to CDC within 24 hours of an order, to the extent such data elements are already available and maintained by the airline.

Identifying individual COVID–19 cases and conducting contact tracing continue to be an important strategy in preventing opportunities for the virus to spread and mutate, particularly to prevent the spread of variants of COVID–19 that are not already prevalent in the United States. Even as more people become fully vaccinated, sub-populations of unvaccinated people and others vulnerable to infection will remain, including people who elect not to be vaccinated, those ineligible for vaccination (currently young children), people with contraindications to vaccination, and people at increased risk for severe illness (including some who may be fully vaccinated, such as those with certain immunocompromising conditions). In areas where spread of the virus has been controlled, rapid identification of imported cases and containment of further transmission through nonpharmaceutical interventions, including isolation of infected people and quarantine of susceptible close contacts, will be essential to prevent resurgence of local epidemics and ultimately end the pandemic.

CDC has taken a variety of additional steps to mitigate the risk that travel poses to the further spread of SARS–CoV–2 and the introduction of its variants into the United States. On October 25, 2021, CDC amended an Order requiring all air passengers two years of age and older traveling to the United States from any foreign country to be tested for SARS–CoV–2 either no more than three days prior to their flight, for those who are fully vaccinated, or no more than one day prior to their flight, for those who are not fully vaccinated. Air passengers may alternatively present documentation of having recovered from COVID–19 in the previous 3 months.[23] On October 25, 2021, CDC also issued an Order implementing a Presidential Proclamation requiring all noncitizens who are nonimmigrants, with limited exceptions, to be fully vaccinated in order to fly into the United States from any foreign country. On January 29, 2021, CDC issued an Order requiring the wearing of masks by persons on any conveyance entering, traveling within, or departing the United States and at U.S. transportation hubs to prevent further spread of SARS–CoV–2.[24] In addition, CDC has posted Level 4 Travel Notices recommending travelers avoid all non-essential travel to more than 150 countries worldwide because of very high rates of COVID–19 in these countries.[25] This Order aligns with these new and existing public health mitigation actions.

Scope of the Order

This Order applies to all passengers and passenger-carrying operations arriving into the United States from a foreign last point of departure (including flights with intermediate stops in the United States between the flight's foreign point of origin and the final destination). Where appropriate, CDC has used Federal Aviation Administration or Department of Transportation regulatory references for ease of reference for the affected industry. As used in the Order, the terms described below have their given meanings.

This Order imposes obligations on ''airlines'', ''operators,'' ''passengers,'' and ''crewmembers.'' ''Airlines'' has the same meaning as in 42 CFR 71.1(b), which includes ''air carriers'' and ''foreign air carriers'' providing ''air transportation'' as those terms are defined in 49 U.S.C. 40102(a)(2), (a)(5), and (a)(21). An ''operator'' is any person [26] that operates an aircraft. To ''operate'' an aircraft means to use, cause to use, or authorize to use aircraft for the purpose of air navigation. ''Operate'' includes piloting an aircraft, with or without the right of legal control (as owner, lessee, or otherwise). An

[18] Regan JJ, Jungerman MR, Lippold SA, et al. Tracing Airline Travelers for a Public Health Investigation: Middle East Respiratory Syndrome Coronavirus (MERS–CoV) Infection in the United States, 2014. Public Health Rep. 2016 Jul–Aug;131(4):552–9. doi: 0.1177/0033354916662213.

[19] Cohen NJ, Brown CM, Alvarado-Ramy F, et al. Travel and Border Health Measures to Prevent the International Spread of Ebola. MMWR Suppl. 2016 Jul 8;65(3):57–67. doi: 10.15585/mmwr.su6503a9.

[20] Dollard P, Griffin I, Berro A, et al. Risk Assessment and Management of COVID–19 Among Travelers Arriving at Designated U.S. Airports, January 17–September 13, 2020. MMWR Morb Mortal Wkly Rep. 2020 Nov 13;69(45):1681–1685. doi: 10.15585/mmwr.mm6945a4.

[21] *https://www.ecfr.gov/current/title-42/chapter-I/subchapter-F/part-71#71.4.*

[22] *https://www.federalregister.gov/documents/2020/02/12/2020-02731/control-of-communicable-diseases-foreign-quarantine.*

[23] 86 FR 7387 and *https://www.cdc.gov/quarantine/fr-proof-negative-test.html.*

[24] 86 FR 8025 and *https://www.cdc.gov/quarantine/masks/mask-travel-guidance.html.*

[25] *https://wwwnc.cdc.gov/travel/noticescovid19.*

[26] A ''person'' is ''an individual, firm, partnership, corporation, company, association, joint-stock association, or governmental entity. It includes a trustee, receiver, assignee, or similar representative of any of them.'' 14 CFR 1.1.

operator can be any person such as an air carrier, a commercial operator (as defined in 14 CFR 1.1), or a non-certificated party. ''Passenger'' means any person who is not a crewmember on any aircraft operation carrying any person (''passenger-carrying operation''). ''Crewmember'' means a person assigned to perform duty in an aircraft during flight time.

Passengers must provide the designated information, to the extent it exists, to airlines and operators. Airlines and operators must collect the designated information from passengers and retain it for 30 days from the flight's departure unless it is otherwise transmitted to the U.S. Government. CDC is requiring a retention period of 30 days because it can take up to 30 days for CDC to receive genetic sequencing information identifying a SARS–CoV–2 variant of concern for which contact tracing beyond the 14-day incubation period of COVID–19 may be warranted. The incubation periods for measles, whooping cough, meningococcal disease, Ebola, and MERS—other communicable diseases for which CDC conducts contact investigations—are all less than 30 days.

Airlines or operators that enter into a contract with U.S. Military services to provide transportation to persons designated by U.S. Military services are exempt from the Order. CDC is exempting these operations because U.S. Military service's standard practice is to collect and retain the designated information and conduct any necessary public health follow-up for passengers on the aircraft that operate in accordance with the U.S. Military service contract with the airline or operator. Airlines and operators that contract with other U.S. Government agencies may be eligible for an exemption on a case-by-case basis if the U.S. Government agency submits a request to CDC and agrees to CDC's required public health conditions, including conducting necessary public health follow-up for passengers. But, in these instances, the U.S. Government agency that is a party to such a contract shall conduct any necessary public health follow-up for passengers and crew. Flights designated as state aircraft under international law (1) by an appropriate United States federal government department or agency, or (2) by a foreign government and granted diplomatic clearance to enter U.S. airspace, are exempt from this Order.

This Order does not alter or affect the requirements under 42 CFR 71.21 that airlines and operators, including Air Medical Transport services, report to CDC any deaths or illnesses onboard flights destined for a U.S. airport.[27] As part of the reporting of any death or illness onboard, passenger contact information must be collected and reported in real time to CDC, in addition to any data transmission required under this Order.[28]

Determinations and Immediate Action

Accordingly, and consistent with 42 CFR 71.4, 71.20, 71.31, and 71.32, I hereby find that international travel into the United States has the potential to exacerbate and accelerate the introduction of SARS–CoV–2 variants not already present (along with other communicable diseases) and that the scope of this pandemic is inherently and necessarily a problem that is global in nature. The collection and transmission of information required by this Order is therefore necessary to prevent the further introduction, transmission, or spread of COVID–19 via air travel into and throughout the United States. The requirements of this Order will enable prompt public health follow-up by public health jurisdictions, allowing them to quickly implement public health mitigation efforts such as isolation of infected persons and contact tracing and management of people exposed to a communicable disease of concern.

In addition, I hereby determine that passengers and crewmembers on flights covered by this Order are or may be at risk of exposure to SARS–CoV–2 and may further the introduction and spread of SARS–CoV–2 variants and other communicable diseases into the United States. Their accurate and complete contact information as provided for in this Order is needed to protect the health of other travelers and U.S. communities.

The CDC has determined that this Order is not a rule within the meaning of the Administrative Procedure Act (APA) but rather an emergency action taken under the existing regulatory authority of 42 CFR 71.4, 71.20, 71.31, and 71.32. The purpose of these sections is to enable CDC to swiftly take targeted actions within the scope of these authorities to prevent the introduction and spread of communicable diseases. Indeed, in response to the current pandemic, CDC published an interim final rule (IFR) [29] for public comment on February 12, 2020, establishing the requirements in 42 CFR 71.4 [30] to collect and transmit designated information upon an order issued by the CDC Director.

Good Cause

In the event that a court finds this Order qualifies as a rule under the APA, there is good cause to dispense with prior notice and comment and a delay in effective date. See 5 U.S.C. 553(b)(B), (d)(3). As more fully explained below, I have determined that good cause exists because the public health emergency caused by COVID–19 and the unpredictability of virus mutations and the recent course of the pandemic make notice-and-comment rulemaking impracticable and contrary to the public health, and by extension the public interest.

The rapidly changing nature of the pandemic requires not only that CDC act swiftly, but also deftly, to ensure that its actions are commensurate with the threat. Given the current case rates and other disease mitigation measures that federal, state, and local jurisdictions are taking across the country, identifying individual cases and conducting contact tracing are critical public health actions urgently needed to prevent opportunities for the virus to spread and further mutate.

The emergence of variants, particularly the Delta variant, has demonstrated the unpredictability of the SARS–CoV–2 virus and the COVID–19 pandemic and has shown how COVID–19 case rates, hospitalizations, and deaths can increase rapidly when a new variant emerges. For example, the Delta variant is more than two times as contagious as previous variants and has spread faster than earlier variants of the SARS–CoV–2 virus.[31] The share of infections from the Delta variant in the United States on May 29, 2021, was under 7%, at a point when the trajectory of the pandemic seemed for the better, but by July 31, 2021, the share of infections with the Delta variant surpassed 94%.[32] In late June, the 7-day moving average of reported cases was only around 12,000. By July 27, just 4 weeks later, the 7-day moving average of cases had increased fivefold and reached over 60,000, a rate similar to the rate before COVID–19 vaccines were widely available. Between July and September, the spread of the Delta variant caused a rapid increase in hospitalizations and deaths, especially

[27] *https://www.cdc.gov/quarantine/air/reporting-deaths-illness/guidance-reporting-onboard-deaths-illnesses.html.*

[28] *https://www.cdc.gov/quarantine/air/reporting-deaths-illness/.*

[29] *https://www.federalregister.gov/documents/2020/02/12/2020-02731/control-of-communicable-diseases-foreign-quarantine.*

[30] *https://www.ecfr.gov/current/title-42/chapter-I/subchapter-F/part-71#71.4.*

[31] *https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html.*

[32] *https://covid.cdc.gov/covid-data-tracker/#variant-proportions.*

in areas with higher levels of community transmission and lower vaccination coverage.[33] [34] The 7-day average for August 4-August 10 for new hospital admissions was a 29.6% increase from the prior 7-day average. The 7-day average for new deaths increased 21% compared to the previous 7-day average. As of October 24, 2021, COVID–19 cases were declining; however, a majority of the United States is still experiencing high community transmission. There have been multiple points throughout the COVID–19 pandemic when cases have swiftly and unexpectedly surged and then declined; therefore, the rapidly changing, unpredictable nature of the COVID–19 pandemic compels CDC to act quickly.

With high transmission rates and low vaccination rates in areas of the United States and around the world, new SARS–CoV–2 variants are expected to occur. New variants may be more transmissible or cause more severe disease, and vaccines and therapeutics may be less effective against these strains. The best way to slow the emergence of new variants is to act quickly to reduce the spread of infection through vaccination layered with additional mitigation measures, including timely and effective case detection and contact tracing and public health follow-up of international travelers.

For these reasons, I hereby conclude that notice-and-comment rulemaking and a delay in the effective date or the Order would defeat the purpose of the Order and endanger the public health, and is, therefore, impracticable and contrary to the public interest. CDC may exercise its enforcement discretion with respect to airlines and operators who are unable to come into compliance on November 8, 2021 despite demonstrated good faith efforts to do so.

Miscellaneous

Similarly, if this Order qualifies as a rule under the APA, the Office of Information and Regulatory Affairs (OIRA) has determined that it would be a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (the Congressional Review Act or CRA), 5 U.S.C. 804(2). Regardless of whether this Order qualifies as a rule under the APA, OIRA has determined that it is an economically significant regulatory action under the definitions provided for those terms in Executive Order 12866. Thus, this action has been reviewed by OIRA. CDC has determined that for the same reasons given above, there would be good cause under the CRA to make the requirements herein effective immediately. 5 U.S.C. 808(2). This Order will cease to be in effect on the earlier of (1) the date that is two incubation periods after the last known case of COVID–19, or (2) when the Secretary determines there is no longer a need for the interim final rule (IFR) [35] published in the **Federal Register** on February 7, 2020. As appropriate, the Secretary will publish a document in the **Federal Register** announcing the expiration date of the IFR.

CDC will separately comply with the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

If any provision of this Order, or the application of any provision to any persons, entities, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any persons, entities, or circumstances other than those to which it is held invalid, shall remain valid and in effect.

Directive

In accordance with 42 CFR 71.4, 71.20, 71.31, and 71.32 as authorized by 42 U.S.C. 264 and 268, it is hereby *ordered:*

1. Definitions

As used in this Order, the term:

'*Airline*' has the same meaning as in 42 CFR 71.1(b);

'*Communicable disease*' has the same meaning as in 42 CFR 71.1(b);

'*Crewmember*' means a person assigned to perform duty in an aircraft during flight time;

'*Designated information*' means the data elements listed below, to the extent that they exist.[36] Data elements listed in subsections (a) through (e) must be provided by the passenger and maintained by the airline or operator for crewmembers and (f) through (m) must be provided to the extent such data elements are already available and maintained by the airline or operator.

(a) Full name (last, first, and, if available, middle or suffix (*e.g.,* Jr.);

(b) Address while in the United States (number and street, city, state or territory, and zip code);

(c) Primary contact phone number to include country and area code, at which the passenger or crewmember can be contacted while in the United States;

(d) Secondary contact phone number to include country and area code, which may be an emergency contact number, a work number, or a home number;

(e) Email address that the passenger or crewmember will routinely check while in the United States;

(f) Date of birth;

(g) Airline name;

(h) Flight number;

(i) City of departure;

(j) Departure date and time;

(k) City of arrival;

(l) Arrival date and time; and

(m) Seat number.

'*Operator*' means any person that operates an aircraft. To ''operate'' an aircraft means to use, cause to use or authorize to use aircraft for the purpose of air navigation. ''Operate'' includes piloting an aircraft, with or without the right of legal control (as owner, lessee, or otherwise). An operator can be any person such as an air carrier, a commercial operator (as defined in 14 CFR 1.1) or a non-certificated party.

'*Passenger*' means any person who is not a crewmember on any aircraft operation carrying any person;

'*United States*' has the same meaning as in 42 CFR 71.1(b).

2. Requirements for Airlines and Operators

(a) This section applies to all passenger-carrying operations conducted on aircraft arriving into the United States from a foreign last point of departure (including flights with intermediate stops in the United States between the flight's foreign point of origin and the final destination). Airlines and operators are required to collect data as soon as practicable but CDC will use enforcement discretion after the Order effective date to allow airlines to come into compliance.

(b) Beginning on flights departing for the United States from a foreign last point of departure after 12:01 a.m. Eastern Standard Time on November 8, 2021 (including flights with intermediate stops in the United States between the flight's foreign origin and the final destination), all airlines and operators of any passenger-carrying operations shall:

(i) Collect the ''designated information'' for all passengers before boarding, but not more than 72 hours before departing from the flight's foreign last point of departure;

(ii) Maintain the ''designated information'' for all crewmembers;

(iii) When collecting the ''designated information,'' notify passengers of the purpose and intent of the information

[33] *https://gis.cdc.gov/grasp/covidnet/COVID19_5.html.*

[34] *https://covid.cdc.gov/covid-data-tracker/#trends_dailydeaths.*

[35] *https://www.federalregister.gov/documents/2020/02/12/2020-02731/control-of-communicable-diseases-foreign-quarantine.*

[36] An individual may not, for example, have an email address or phone number, in which case the individual would not be required to provide one.

collection, that the obligation to provide complete and accurate information is a United States Government requirement, and that failure to provide complete and accurate information may result in criminal penalties, as set forth herein. The airline or operator must also obtain confirmation from each passenger that the information provided is complete and accurate; and

(iv) Retain the ''designated information'' under subparagraphs 2(b)(i) and 2(b)(ii) for each flight for a minimum of 30 days from the flight's departure and, within 24 hours of a request from the CDC Director, transmit it to CDC through secure, electronic means approved by CDC.[37] Data retention is not required for those airlines and operators who choose to otherwise securely transmit data using established DHS data systems.

Any entities covered under section 2 that fail to comply with section 2 may be subject to criminal penalties under, *inter alia,* 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571. Willfully giving false or misleading information to the government may result in criminal penalties under, *inter alia,* 18 U.S.C. 1001.

3. Requirements for Passengers

This section applies to any passenger on a flight covered under this Order, including passengers with intermediate stops in the United States between the flight's foreign point of origin and the final destination. Beginning on flights departing for the United States from a foreign last point of departure after 12:01 a.m. Eastern Standard Time on November 8, 2021, the passenger or the passenger's authorized representative shall—

(i) Accurately provide the ''designated information'' as instructed by the airline or operator before boarding a flight to the United States insofar as the information exists for the passenger;

(ii) Acknowledge the airline's or operator's notification of the purpose and intent of this information collection, that the obligation to provide complete and accurate information is a United States Government requirement, and that failure to provide complete and accurate information may result in criminal penalties; and,

(iii) Confirm that the provided ''designated information'' is complete and accurate.

An authorized representative (for example, immediate family member, legal guardian, or travel agent) may provide the ''designated information'' and acknowledge the airline's or operator's notification on behalf of the passenger, including on behalf of a minor or other passenger who is unable to do so on his or her own behalf, but the information provided must be specific to the individual passenger (*e.g.,* agents may not list contact information for the travel agency or provide one telephone number or email address for an entire group of unrelated persons).

Any passenger or authorized representative who fails to comply with the requirements of section 3 may be subject to criminal penalties under, *inter alia,* 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571. Willfully giving false or misleading information to the government may result in criminal penalties under, *inter alia,* 18 U.S.C. 1001.

4. Exemptions

This Order does not apply to the following:

(a) Any airline or operator that enters into a contract with the U.S. Military services to provide transportation to persons designated by the U.S. Military service is exempt from this Order for flights covered under the contract. The U.S. Military service typically collects and retains the ''designated information'' and conducts any necessary public health follow-up for passengers on the aircraft that operate in accordance with the U.S. Military service contract with the airline or operator.

(b) Any airline or operator that enters into a contract with another U.S. Government agency may be eligible for an exemption on a case-by-case basis with approval from the CDC Director. Any request for this exemption must be made to CDC and is subject to any requirement or limitation established by the CDC Director, including that the U.S. Government agency that is a party to such a contract shall conduct any necessary public health follow-up for passengers and crew.

(c) Any airline or operator designated as state aircraft under international law (1) by an appropriate United States federal government department or agency, or (2) by a foreign government and granted diplomatic clearance to enter U.S. airspace.

5. Privacy

CDC intends to use the ''designated information'' only for public health follow-up, such as education, treatment, prophylaxis, or other appropriate public health interventions, including travel restrictions. CDC will maintain and use the ''designated information'' called for in this Order in accordance with the Privacy Act of 1974 (5 U.S.C. 552a) and its applicable System of Record Notice.[38] As noted in the System of Records Notice, CDC retains contact tracing information until the contact tracing investigation is complete or no longer than 12 months. Personally identifiable information may be used and shared only for lawful purposes, including with authorized personnel of the U.S. Department of Health and Human Services, state and local public health departments, and other cooperating authorities, as authorized by law. CDC will retain, use, delete, or otherwise destroy the ''designated information'' in accordance with the Federal Records Act, applicable Privacy Act System of Records notice, and other applicable law.

However, if ''designated information'' is transmitted by airlines via an established DHS data system, DHS will integrate the data into the DHS Automated Targeting System (ATS) [39] and use it for passenger screening. DHS may use the data for any use permitted by the ATS System of Records Notice (SORN) [40] and will retain it for a minimum of fifteen years, in accordance with the SORN. Permitted uses of established data systems, including ATS, include but are not limited to immigration enforcement, law enforcement, anti-terrorism, national security, and border security. DHS shares passenger data with other law enforcement and national security partners pursuant to agreements with those partners for use throughout a period of time specified by the relevant agreement, or according to the recipient agency's SORN or Attorney General-approved intelligence oversight guidelines.

CDC may modify this Order by an updated publication in the **Federal Register**.

Authority

The CDC Director is issuing this Order pursuant to Sections 361 and 365 of the Public Health Service (PHS) Act, 42 U.S.C. 264 and 268, and implementing

[37] *https://www.cdc.gov/quarantine/order-collect-ti.html.*

[38] *https://www.cdc.gov/sornnotice/09-20-0171.htm.*

[39] *https://www.dhs.gov/sites/default/files/publications/privacy-pia-cbp006-ats-may2021.pdf.*

[40] *https://www.gpo.gov/fdsys/pkg/FR-2015-03-13/html/2015-05798.htm.*

regulations at 42 CFR 71.4, 71.20, 71.31, and 71.32.

Sherri Berger,

Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2021–24386 Filed 11–3–21; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Delegation of Authority

Notice is hereby given that pursuant to Section 222 of the Public Health Service Act [42 U.S.C. 217a], as amended, I have delegated to the Director, Centers for Disease Control and Prevention (CDC), authority to appoint temporary members to the National Institute for Occupational Safety and Health's Safety and Occupational Health Study Section (SOHSS). This authority may be redelegated by the CDC Director.

This delegation supersedes the June 7, 2016, delegation concerning this authority.

This delegation became effective upon date of signature. In addition, I affirmed and ratified any actions taken by the Director, CDC or her subordinates that involved the exercise of the authorities delegated herein, or substantially similar authorities vested in me by prior annual HHS appropriations acts, prior to the effective date of the delegation.

Dated: November 2, 2021.

Xavier Becerra,

Secretary.

[FR Doc. 2021–24249 Filed 11–4–21; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Requirement for Negative Pre-Departure COVID–19 Test Result or Documentation of Recovery From COVID–19 for All Airline or Other Aircraft Passengers Arriving Into the United States From Any Foreign Country

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of agency amended order.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces an Amended Order requiring negative pre-departure COVID–19 test results or documentation of recovery from COVID–19 for all airline or other aircraft passengers arriving into the United States from any foreign country. This Amended Order was signed by the CDC Director on October 25, 2021, and supersedes the previous Order signed by the CDC Director on January 25, 2021.

DATES: This Amended Order will become effective at 12:01 a.m. on November 8, 2021.

FOR FURTHER INFORMATION CONTACT: Jennifer Buigut, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329. Telephone: 404–498–1600. Email: *dgmqpolicyoffice@cdc.gov.*

SUPPLEMENTARY INFORMATION: This Amended Order updates COVID–19 testing requirements for air passengers 2 years of age and older boarding a flight to the United States, depending on their COVID–19 vaccination status.

This Amended Order prohibits the boarding of any passenger 2 years of age and older on any airline or aircraft destined to the United States from a foreign country unless the passenger presents:

(1) Paper or digital documentation of a negative pre-departure viral test result for SARS–CoV–2, the virus that causes COVID–19, that meets one of the following requirements:

- For passengers who are fully vaccinated against COVID–19, the viral test must be conducted on a specimen collected no more than 3 days before the flight's departure from a foreign country.
- For passengers not fully vaccinated against COVID–19, the viral test must be conducted on a specimen collected no more than 1 day before the flight's departure from a foreign country.

Or

(2) Paper or digital documentation of recovery from COVID–19 in the form of both:

- A positive viral test result conducted on a specimen collected no more than 90 days before the flight; and
- A letter from a licensed health care provider or public health official stating that the passenger has been cleared for travel.

This Amended Order also constitutes a controlled free pratique to any airline or other aircraft operator with an aircraft arriving into the United States. Pursuant to this controlled free pratique, the airline or other aircraft operator must comply with the requirements outlined in the Amended Order.

A copy of the Amended Order and Passenger Attestation form is provided below. A copy of the signed Amended Order and Passenger Attestation form can be found at *https://www.cdc.gov/quarantine/fr-proof-negative-test.html.*

Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

Notice and Amended Order Under Section 361 of the Public Health Service Act (42 U.S.C. 264) and 42 Code of Federal Regulations 71.20 & 71.31(b)

Requirement for Negative Pre-Departure COVID–19 Test Result or Documentation of Recovery From COVID–19 for All Airline or Other Aircraft Passengers Arriving Into the United States From Any Foreign Country

Summary

Pursuant to 42 CFR 71.20, 71.31(b) and as set forth in greater detail below, this Notice and Amended Order [1] prohibits the boarding of any passenger—2 years of age or older—on any aircraft destined to the United States [2] from a foreign country unless the passenger [3] presents:

(1) Paper or digital documentation of a negative pre-departure viral test result for SARS–CoV–2, the virus that causes COVID–19, that meets one of the following requirements:

- For passengers who are fully vaccinated against COVID–19, the viral test must be conducted on a specimen collected no more than 3 calendar days before the flight's departure from a foreign country (*Qualifying Test for Fully Vaccinated*).
- For passengers who are not fully vaccinated against COVID–19, the viral test must be conducted on a specimen collected no more than 1 calendar day before the flight's departure from a foreign country (*Qualifying Test for Not Fully Vaccinated*).

Or

(2) Paper or digital documentation of recovery from COVID–19 in the form of both:

[1] This Amended Order supersedes the previous order signed by the Centers for Disease Control and Prevention (CDC) Director on January 25, 2021.

[2] This includes any flight, regardless of whether the United States is final destination or connection to another country.

[3] A parent or other authorized individual may present the required documentation on behalf of a passenger 2–17 years of age. An authorized individual may act on behalf of any passenger who is unable to act on their own behalf (*e.g.,* by reason of age, or physical or mental impairment).

• A positive viral test result conducted on a specimen collected no more than 90 calendar days before the flight; *and*

• A letter from a licensed healthcare provider or public health official stating that the passenger has been cleared for travel (*Documentation of Recovery*).

The option to present *Documentation of Recovery* is available to passengers regardless of their vaccination status.

Passengers who have a *Qualifying Test for Fully Vaccinated, i.e.,* a negative pre-departure viral test conducted on a specimen collected no more than 3 calendar days before the flight's departure from a foreign country, must have paper or digital documentation of being fully vaccinated with an *Accepted COVID–19 Vaccine* (*Proof of Being Fully Vaccinated Against COVID–19*).

Passengers who have a *Qualifying Test for Not Fully Vaccinated, i.e.,* a negative pre-departure viral test conducted on a specimen collected no more than 1 calendar day before the flight's departure from a foreign country, do not need to present *Proof of Being Fully Vaccinated Against COVID–19.*

Alternatively, if a passenger has tested positive for SARS–CoV–2 on a specimen collected no more than 90 calendar days before the flight's departure and recovered from COVID–19 (*i.e.,* met CDC criteria to end isolation),[4] the passenger may instead travel with paper or digital documentation of the positive viral test result that confirms the previous SARS–CoV–2 infection and a letter from a licensed healthcare provider or public health official stating that the passenger has been cleared for travel (*Documentation of Recovery*).

Each passenger must retain paper or digital documentation presented to the airline or other aircraft operator reflecting one of the following:

• Negative result for *Qualifying Test for Fully Vaccinated* plus *Proof of Being Fully Vaccinated Against COVID–19;*

• Negative result for the *Qualifying Test for Not Fully Vaccinated; or*

• *Documentation of Recovery* from COVID–19.

A passenger, or the passenger's authorized representative, must also produce such documentation upon request to any U.S. government official or a cooperating state or local public health authority.

Pursuant to 42 CFR 71.31(b) and as set forth in greater detail below, this Notice and Amended Order constitute a controlled free pratique to any airline or other aircraft operator with an aircraft arriving in the United States.[5] Pursuant to this controlled free pratique, the airline or other aircraft operator must comply with the following conditions to receive permission for the aircraft to enter and disembark passengers in the United States:

• Airline or other aircraft operator must confirm that every passenger onboard the aircraft based on vaccination status has documentation of a negative result for a *Qualifying Test for Fully Vaccinated* plus *Proof of Being Fully Vaccinated Against COVID–19,* a negative result for a *Qualifying Test for Not Fully Vaccinated,* or *Documentation of Recovery.*

• Airline or other aircraft operator must verify that every passenger onboard the aircraft based on vaccination status has attested to receiving a negative result for the *Qualifying Test for Fully Vaccinated* plus being fully vaccinated, receiving a negative result for the *Qualifying Test for Not Fully Vaccinated,* or having tested positive for SARS–CoV–2 on a specimen collected no more than 90 calendar days before the flight and been cleared to travel as *Documentation of Recovery.*[6]

Statement of Intent

This Order shall be interpreted and implemented to achieve the following paramount objectives:

• Preservation of human life;

• Preventing the further introduction, transmission, and spread of the virus that causes COVID–19 into the United States, including new virus variants;

• Preserving the health and safety of crew members, passengers, airport personnel, and communities; and

• Preserving hospital, healthcare, and emergency response resources within the United States.

Definitions

Accepted COVID–19 Vaccine means:

• A vaccine authorized for emergency use or approved by the U.S. Food and Drug Administration; [7] or

• A vaccine listed for emergency use by the World Health Organization (WHO); [8] or

• A vaccine or combination of vaccines [9] listed by CDC in CDC's Technical Instructions for Implementing Presidential Proclamation Advancing Safe Resumption of Global Travel During the COVID–19 Pandemic and CDC's Order.

Aircraft shall have the same definition as under 49 U.S.C. 40102(a)(6). ''Aircraft'' includes, but is not limited to, commercial, general aviation, and private aircraft destined for the United States from a foreign country.

Aircraft Operator means an individual or organization causing or authorizing the operation of an aircraft.

Airline shall have the same definition as under 42 CFR 71.1(b).

Attest/Attestation means having completed the attestation in Attachment A.[10] Such attestation may be completed in paper or digital form. The attestation is a statement, writing, entry, or other representation under 18 U.S.C. 1001.[11]

Documentation of Recovery means paper or digital documentation of recovery from COVID–19 in the form of a positive SARS–CoV–2 viral test result

[4] *https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html.*

[5] On October 25, 2021, the President issued a Proclamation pursuant to Sections1182(f) and 1185(a)(1) of Title 8, and Section 301 of Title 3, United States Code, titled, ''Advancing the Safe Resumption of Global Travel During the COVID–19 Pandemic.'' Pursuant to this Proclamation. The President has implemented a global suspension and restriction on entry for noncitizens who are nonimmigrants seeking to enter the United States by air travel and who are not fully vaccinated against COVID–19. This amended CDC Order complements and advances the safe resumption of global travel.

[6] A parent or other authorized individual may present the required documentation on behalf of a passenger 2–17 years of age. An authorized individual may act on behalf of any passenger who is unable to act on their own behalf (*e.g.,* by reason of age, or physical or mental impairment).

[7] For a list of vaccines approved or authorized in the United States to prevent COVID–19, see *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html.*

[8] See WHO's website for more information about WHO emergency use-listed COVID–19 vaccines.

[9] CDC has not recommended the use of heterologous (*i.e.,* mix-and-match) primary series. However, the use of such strategies (including mixing of mRNA, adenoviral, and mRNA plus adenoviral products) is increasingly common in many countries outside of the United States. Accordingly, additional vaccinations or combinations of vaccinations may be listed in CDC's in Technical Instructions for Implementing Presidential Proclamation Advancing Safe Resumption of Global Travel During the COVID–19 Pandemic and CDC's Order for purposes of the interpretation of vaccination records.

[10] CDC has provided a combined passenger disclosure and attestation that fulfills the requirements of CDC Orders: *Requirement for Proof of Negative COVID–19 Test Result or Recovery from COVID–19 for All Airline Passengers Arriving into the United States* and *Order Implementing Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID–19 Pandemic.*

[11] CDC encourages airlines and aircraft operators to incorporate the attestation into paperless check-in processes. An airline or aircraft operator may use a third party (including a third-party application) to collect attestations, including to provide translations. However, an airline or aircraft operator has sole legal responsibility to provide and collect attestations, to ensure the accuracy of any translation, and to comply with all other obligations under this Order. An airline or aircraft operator is responsible for any failure of a third party to comply with this Order. An airline or aircraft operator may not shift any legal responsibility to a third party.

and a letter from a licensed healthcare provider or public health official stating that the person has been cleared for travel (*i.e.,* has recovered).[12] [13] The viral test must have been conducted on a specimen collected no more than 90 calendar days before the departure of the flight.

Foreign country means anywhere that is not a state, territory, or possession of the United States.

Fully Vaccinated Against COVID–19 means it has been:

- 2 weeks (14 days) or more since a person received one dose of an accepted single-dose series COVID–19 vaccine; OR
- 2 weeks (14 days) or more since a person's second dose in a 2-dose series of an accepted COVID–19 vaccine; OR
- 2 weeks (14 days) or more since a person received a complete series of a vaccine or combination of vaccines listed by CDC in CDC's Technical Instructions for Implementing Presidential Proclamation Advancing Safe Resumption of Global Travel During the COVID–19 Pandemic and CDC's Order.

Not Fully Vaccinated Against COVID–19 means a person does not meet the definition of *Fully Vaccinated Against COVID–19.*

Proof of Being Fully Vaccinated against COVID–19 means a person has an acceptable paper or digital format of a vaccination record or a verifiable vaccination record confirming that the person is Fully Vaccinated Against COVID–19 as defined and listed by CDC in CDC's Technical Instructions for Implementing Presidential Proclamation Advancing Safe Resumption of Global Travel During the COVID–19 Pandemic and CDC's Order.

Qualifying Test for Fully Vaccinated means a negative result on a SARS–CoV–2 viral test that was conducted on a specimen collected no more than *3 calendar days* before the flight's departure from a foreign country to the United States for passengers who have *Proof of Being Fully Vaccinated Against COVID–19.*

Qualifying Test for Not Fully Vaccinated means a negative result on a SARS–CoV–2 viral test that was conducted on a specimen collected no more than *1 calendar day* before the flight's departure from a foreign country to the United States for passengers who do not have *Proof of Being Fully Vaccinated Against COVID–19.*

United States has the same definition as ''United States'' in 42 CFR 71.1(b), meaning ''the 50 States, District of Columbia, and the territories (also known as possessions) of the United States, including American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands.''

Viral test means a viral detection test for current infection (*i.e.,* a nucleic acid amplification test [NAAT] or a viral antigen test) approved or authorized by the relevant national authority or the U.S. Food and Drug Administration for the detection of SARS–CoV–2.

Exemptions

The following categories of individuals and organizations are exempt from the requirements of this Amended Order:

- Crew members of airlines or other aircraft operators if they follow industry standard protocols for the prevention of COVID–19 as set forth in relevant Safety Alerts for Operators (SAFOs) issued by the Federal Aviation Administration (FAA).[14]
- Airlines or other aircraft operators transporting passengers with COVID–19 pursuant to CDC authorization and in accordance with CDC guidance.[15]
- U.S. federal law enforcement personnel on official orders who are traveling for the purpose of carrying out a law enforcement function, provided they are covered under an occupational health and safety program that takes measures to ensure personnel are not symptomatic or otherwise at increased risk of spreading COVID–19 during travel. Those traveling for training or other business purposes remain subject to the requirements of this Order.
- U.S. military personnel, including civilian employees, dependents, contractors, and other U.S. government employees when traveling on U.S. military assets (including whole aircraft charter operators), if such individuals are under competent military or U.S government travel orders and observing U.S. Department of Defense guidance to prevent the transmission of COVID–19 as set forth in *Force Protection Guidance Supplement 20—Department of Defense Guidance for Personnel Traveling During the Coronavirus Disease 2019 Pandemic* (April 12, 2021) including its testing guidance.[16]
- Individuals and organizations for which the issuance of a humanitarian exemption is necessary based on both: (1) Exigent circumstances where emergency travel is required to preserve health and safety (*e.g.,* emergency medical evacuations) and (2) where pre-departure testing cannot be accessed or completed before travel because of exigent circumstances. Additional conditions may be placed on those granted such exemptions, including but not limited to, observing precautions during travel, providing consent to post-arrival testing, and/or self-quarantine after arrival in the United States, as may be directed by federal, state, territorial, tribal or local public health authorities to reduce the risk of transmission.

Background

A. COVID–19 Pandemic

Since January 2020, the respiratory disease known as ''COVID–19,'' caused by a novel coronavirus (SARS–CoV–2), has spread globally, including cases reported in all 50 states within the United States, plus the District of Columbia and all U.S. territories. As of October 22, 2021, there have been over 242,000,000 million cases of COVID–19 globally, resulting in over 4,900,000deaths.[17] More than 45,000,000 cases have been identified in the United States, with new cases reported daily, and over 733,000 deaths have been attributed to the disease. A renewed surge in cases in the United States began in early July 2021; daily case counts rose from 19,000 cases on July 1, 2021 to 159,000 cases on September 1, 2021. While cases are currently decreasing in the United States, during the entirety of this pandemic, cases have tended to surge in waves, including after high-volume travel periods, with 4 waves as of October 2021.[18] Therefore, additional

[12] Healthcare providers and public health officials should follow CDC guidance in clearing patients for travel to the United States. Applicable guidance is available at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html.*

[13] A letter from a healthcare provider or a public health official that clears the person to end isolation (*e.g.,* to return to work or school), can also be used to show that the person has been cleared to travel, even if travel is not specifically mentioned in the letter.

[14] Airlines, aircraft operators, and their crew members may follow stricter protocols for crew and passenger health, including testing protocols. SAFO 20009, COVID–19: Updated Interim Occupational Health and Safety Guidance for Air Carriers and Crews, available at *https://www.faa.gov/other_visit/aviation_industry/airline_operators/airline_safety/safo/all_safos/media/2020/SAFO20009.pdf.*

[15] Interim Guidance for Transporting or Arranging Transportation by Air into, from, or within the United States of People with COVID–19 or COVID–19 Exposure, available at *https://www.cdc.gov/quarantine/interim-guidance-transporting.html.*

[16] Force Protection Guidance Supplement 20—Department of Defense Guidance for Personnel Traveling During the Coronavirus Disease 2019 Pandemic, available at *https://media.defense.gov/2021/Apr/16/2002622876/-1/-1/1/MEMORANDUM-FOR-FORCE-HEALTH-PROTECTION-GUIDANCE-SUPPLEMENT%2020-DEPARTMENT-OF-DEFENSE-GUIDANCE-FOR-PERSONNEL-TRAVELING-DURING-THE-CORONAVIRUS-DISEASE-2019-PANDEMIC.PDF.*

[17] *https://covid19.who.int/.*

[18] *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

surges of cases and deaths are very possible.

Many countries have begun widespread vaccine administration; however, 98 countries continue to experience high or substantial incidence rates (>50 cases per 100,000 people in the last seven days) and 65 countries, including the United States, are experiencing a high incidence of reported new cases at this time.[19]

SARS–CoV–2 spreads mainly from person-to-person through respiratory fluids released during exhalation, such as when an infected person coughs, sneezes, or talks.

Exposure to these respiratory fluids occurs in three principal ways: (1) Inhalation of very fine respiratory droplets and aerosol particles, (2) deposition of respiratory droplets and particles on exposed mucous membranes in the mouth, nose, or eye by direct splashes and sprays, and (3) touching mucous membranes with hands that have been soiled either directly by virus-containing respiratory fluids or indirectly by touching surfaces with virus on them.[20] [21] Spread is more likely when people are in close contact with one another (within about 6 feet), especially in crowded or poorly ventilated indoor settings. Persons who are not fully vaccinated, including those with asymptomatic or pre-symptomatic infections, are significant contributors to community SARS–CoV–2 transmission and occurrence of COVID–19.[22] [23]

Among adults, the risk for severe illness from COVID–19 increases with age, with older adults at highest risk.[24] Severe illness means that persons with COVID–19 may require hospitalization, intensive care, or a ventilator to help them breathe, and may die. People of any age with certain underlying medical conditions (*e.g.,* cancer, obesity, serious heart conditions, diabetes, conditions that weaken the immune system) are at increased risk for severe illness from COVID–19.[25]

B. Emergence of Variants of Concern

New variants of SARS–CoV–2 have emerged globally, several of which have been identified as variants of concern, including the Delta variant. Some variants are more transmissible and some may cause more severe disease, which can lead to more hospitalizations, and deaths among infected individuals.[26] Furthermore, findings suggest some variants may reduce levels of virus neutralization by antibodies generated during previous infection or vaccination, resulting in reduced effectiveness of treatments or vaccines, or increased diagnostic detection failures.[27] The emergence of variants that substantially decreases the effectiveness of available vaccines against severe or deadly disease is a primary public health concern. While such a variant of high consequence has not yet been identified, so long as new variants of SARS–CoV–2 continue to emerge and circulate, the potential for such a variant remains not only a possibility, but a current reality.

As the virus spreads, it has new opportunities to change (mutate) and may become more difficult to control. While it is known and expected that viruses change through mutation leading to the emergence of new variants, the existing Delta variant is particularly concerning because it spreads more easily than previous variants of SARS–CoV–2.[28] The Delta variant has rapidly become the predominant strain in the United States with more than 99% of U.S. cases attributed to it as of October 16, 2021.[29] Globally, 193 countries have reported cases of the Delta variant as of October 19, 2021.[30]

Of critical significance for this Amended Order, the Delta variant has increased transmissibility, especially among persons who are not fully vaccinated, and increases the risk of infection in fully vaccinated individuals in the absence of other mitigation strategies, such as mask wearing.[31] For persons not fully vaccinated, Delta is a formidable threat and the surge in cases since the summer of 2021 has been fueled in part by low vaccination coverage in many U.S. communities.[32] Available evidence suggests all three vaccines currently approved or authorized in the United States provide significant protection.[33] However, a small proportion of people who are fully vaccinated may become infected, a risk that is increased with the Delta variant; emerging evidence suggests that fully vaccinated persons who do become infected with the Delta variant are at risk for transmitting it to others.[34] However, the vast majority of fully vaccinated individuals continue to be protected from severe illness, hospitalization, and death, even with the Delta variant.

C. Availability of Testing and Vaccines in the United States and Globally

The potential for asymptomatic and pre-symptomatic transmission makes testing an essential part of COVID–19 mitigation protocols. With the additional testing capacity available through antigen tests, infected persons can be identified more rapidly so they can be isolated until they no longer pose a risk of spreading the virus and their

[19] *https://covid19.who.int/.*

[20] *Scientific Brief: SARS–CoV–2 Transmission,* Centers for Disease Control and Prevention (May 7, 2021), *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html.*

[21] *Science Brief: SARS–CoV–2 and Surface (Fomite) Transmission for Indoor Community Environments,* Centers for Disease Control and Prevention (Apr. 5, 2021), *https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/surface-transmission.html.*

[22] Moghadas SM, Fitzpatrick MC, Sah P, et al. The implications of silent transmission for the control of COVID–19 outbreaks. *Proc Natl Acad Sci U S A.* 2020;117(30):17513–17515.10.1073/pnas.2008373117, available at *https://www.ncbi.nlm.nih.gov/pubmed/32632012.*

[23] Johansson MA, Quandelacy TM, Kada S, et al. SARS–CoV–2 Transmission from People Without COVID–19 Symptoms. Johansson MA, et al. JAMA Netw Open. 2021 January4;4(1):e2035057. doi: 10.1001/jamanetworkopen.2020.35057.

[24] CDC. COVID–19 Risks and Vaccine Information for Older Adults *https://www.cdc.gov/aging/covid19/covid19-older-adults.html.*

[25] People with Certain Medical Conditions *https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.*

[26] Dougherty K, Mannell M, Naqvi O, Matson D, Stone J. SARS–CoV–2 B.1.617.2 (Delta) Variant COVID–19 Outbreak Associated with a Gymnastics Facility—Oklahoma, April–May 2021. MMWR Morb Mortal Wkly Rep 2021;70:1004–1007. DOI: *http://dx.doi.org/10.15585/mmwr.mm7028e2* (describing a B.1.617.2 (Delta) Variant COVID–19 outbreak associated with a gymnastics facility and finding that the Delta variant is highly transmissible in indoor sports settings and households, which might lead to increased incidence rates).

[27] SARS–CoV–2 Variant Classifications and Definitions, Centers for Disease Control and Prevention, *https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html#Concern.*

[28] Li B, Deng A, Li K, et al. Viral Infection and Transmission in a Large Well-Traced Outbreak Caused by the Delta SARS–CoV–2 Variant. medRxiv. 2021 Jul 12; *https://doi.org/10.1101/2021.07.07.21260122.*

[29] *https://covid.cdc.gov/covid-data-tracker/#variant-proportions.*

[30] *https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---19-october-2021.*

[31] Delta Variant: What We Know About the Science, *https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html.*

[32] COVID Data Tracker Weekly Review, Interpretive Summary for July 23, 2021, Centers for Disease Control and Prevention, *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/past-reports/07232021.html https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/past-reports/07232021.html.*

[33] *Science Brief: COVID–19 Vaccines and Vaccination,* Centers for Disease Control and Prevention, *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html.* Other vaccines, particularly the one manufactured by AstraZeneca, show reduced efficacy against infection with certain variants but may still protect against severe disease; at the time of the issuance of this Order, the FDA has not authorized the AstraZeneca COVID–19 vaccine for use in the United States.

[34] Delta Variant: What We Know About the Science, *https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html.*

close contacts can be identified and quarantined.[35]

COVID–19 vaccines are now widely available in the United States, and vaccination is recommended for all people 12 years of age and older. As of October 23, 2021, approximately 190.4 million people in the United States (67.1% of the population 12 years or older) have been fully vaccinated and over 219 million people in the United States (77.6% of the population 12 years or older) have received at least one dose.[36] However, after a rapid increase in the proportion of the U.S. population vaccinated against COVID–19 in the first months of 2021, vaccinations administered in the United States have slowed, particularly in those under the age of 65 years.[37]

The combination of the substantial proportion of the population that remains not fully vaccinated either through ineligibility (in the case of children under 12 years) or by choice, and the extreme transmissibility of the Delta variant resulted in sharp increases in COVID–19 cases in the United States over the summer and early fall of 2021, primarily and disproportionately affecting persons not fully vaccinated.

The availability of COVID–19 vaccines is also rising globally but is still small when compared to the availability of vaccines in the United States and a handful of other countries.[38] Approximately 6.84 billion doses of COVID–19 vaccine have been administered globally. However, vaccine supplies and testing capacity remain limited in many low-income countries.[39] [40] Outbreaks linked to international travel caused by unvaccinated and untested travelers have the potential to increase the introduction, transmission, and spread of COVID–19 variants into the United States. Many other countries around the world are making efforts to increase COVID–19 vaccination for their populations, with some considering or adding proof of vaccination requirements as a condition for entry.[41] [42] [43]

CDC is aware of a rising number of SARS–CoV–2 infections in vaccinated individuals;[44] since vaccines are not 100% effective at preventing infection, some people who are fully vaccinated may still get COVID–19. While the vaccines currently approved or authorized by the FDA are successful in preventing severe illness and death, including from the highly transmissible Delta variant, infections and even mild to moderate illness have been documented in a small percentage of vaccinated persons. However, studies so far show that vaccinated people are 5 times less likely to be infected and more than 10 times less likely to experience hospitalization or death due to COVID–19 than people who are not fully vaccinated.[45] The emergence of the more transmissible Delta variant, as well as the potential emergence of a variant of high consequence that could reduce the effectiveness of treatments or vaccines, increases the urgency to expand vaccination coverage.

D. Justification for Continued Pre-Departure Testing

On December 25, 2020, in response to a new COVID–19 variant (now referred to as the Alpha variant[46]) spreading in the United Kingdom (UK), CDC issued an Order requiring proof of a negative viral test result for all air passengers 2 years of age and older arriving from the UK to the United States. A month later, cases, including those from the Alpha variant, continued to increase significantly, and variants of concern were identified in other countries, leading to CDC issuing an Order on January 25, 2021 requiring all air passengers 2 years of age and older traveling from any foreign country to show a negative pre-departure COVID–19 test result or documentation of recovery from COVID–19 in the previous 90 calendar days before boarding a flight to the United States.

Testing for SARS–CoV–2 infection is a proactive, risk-based approach that is not dependent on the infecting variant. This risk-based testing approach has been addressed in CDC guidance and the Runway to Recovery guidance jointly issued by the Departments of Transportation, Homeland Security, and Health and Human Services.[47] Most countries now use testing in some form to monitor risk and control introduction and spread of SARS–CoV–2.[48] With case counts and deaths due to COVID–19, particularly the Delta variant, continuing to increase around the globe, the high proportion of unvaccinated people in the United States and around the world, and infected people with asymptomatic or pre-symptomatic infections, the United States is taking a multi-layered approach to combatting COVID–19, concurrently preventing and slowing the continued introduction of cases and further spread of the virus within U.S. communities. Vaccination is the most important measure for reducing risk for SARS–CoV–2 transmission during travel and in avoiding severe illness, hospitalization, and death; however, infections in fully vaccinated people indicate that vaccination is a necessary but not sufficient measure; testing of these travelers is still necessary and thus required.

Pre-departure testing does not eliminate all risk. However, when pre-departure testing is combined with other measures such as self-monitoring for symptoms of COVID–19, wearing masks, physical distancing, and hand hygiene, it can make travel safer by reducing spread on conveyances, in transportation hubs, and at destinations. CDC recommends all international travelers get a viral test 3–5 days after arrival at their U.S. destination, combined with self-monitoring. Additionally, CDC recommends international travelers who are not fully vaccinated stay home (or in a comparable location such as a hotel room) and self-quarantine for a full 7

[35] *See* COVID–19 Testing and Diagnostics Working Group (TDWG). U.S. Department of Health and Human Services (HHS), *https://www.hhs.gov/coronavirus/testing/testing-diagnostics-working-group/index.html.* (defining the role of the COVID–19 TDWG, which develops testing-related guidance and provides targeted investments to expand the available testing supply and maximize testing capacity).

[36] *https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.*

[37] Ibid.

[38] *See* ''PAHO Director calls for fair and broad access to COVID–19 vaccines for Latin America and the Caribbean,'' Pan American Health Organization, *https://www.paho.org/en/news/7-7-2021-paho-director-calls-fair-and-broad-access-covid-19-vaccines-latin-america-and* (noting the discrepancies in vaccine availability coverage among North, Central, and South American countries).

[39] *https://ourworldindata.org/covid-vaccinations.*

[40] *https://ourworldindata.org/coronavirus-testing#testing-vs-gdp-per-capita.*

[41] *See* CNN Travel, New Zealand says foreign nationals must have coronavirus vaccination to enter country from November, *https://www.cnn.com/travel/article/new-zealand-travel-vaccination-covid-lockdown-ardern-intl/index.html.*

[42] *See* CNN Canada issues COVID–19 vaccine mandate for travelers 12 or older on trains and planes, *https://www.cnn.com/travel/article/canada-trudeau-vaccine-mandate/index.html.*

[43] *https://www.forbes.com/sites/geoffwhitmore/2021/10/20/covid-19-vaccine-mandates-for-travel/?sh=23fc0cdd4edb.*

[44] *COVID–19 Vaccine Breakthrough Case Investigation and Reporting, https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html.*

[45] Scobie HM, Johnson AG, Suthar AB, et al. Monitoring Incidence of COVID–19 Cases, Hospitalizations, and Deaths, by Vaccination Status—13 U.S. Jurisdictions, April 4–July 17, 2021. MMWR Morb Mortal Wkly Rep. 2021;70(37):1284–1290. Published 2021 Sep 17. doi:10.15585/mmwr.mm7037e1.

[46] SARS–CoV–2 Variant Classifications and Definitions, *https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html.*

[47] Runway to Recovery 1.1, December 21, 2020, available at *https://www.transportation.gov/briefing-room/runway-recovery-11.*

[48] *https://ourworldindata.org/coronavirus-testing#testing-and-contact-tracing-policy.*

days after travel, or for 10 days if they do not get tested, to further reduce the risk of translocating the virus into destination communities.[49]

People who have recovered from COVID–19 can continue to shed detectable but non-infectious SARS–CoV–2 RNA in upper respiratory specimens for up to 3 months after illness onset.[50] For this reason, CDC does not recommend retesting of persons previously diagnosed with COVID–19 within 3 months after the date of symptom onset (or the date of first positive viral diagnostic test if their infection was asymptomatic) for the initial SARS–CoV–2 infection, unless they have symptoms of COVID–19. People who develop any symptoms of COVID–19 during this 90-day period following infection should not travel and should consult a healthcare provider who can evaluate for other causes of their symptoms and determine if testing is needed. This guidance may be updated as additional information about people who have recovered from COVID–19 becomes available.

E. Pre-Departure Testing Requirements Based on Vaccination Status

Recent CDC modeling that incorporated the transmission characteristics of the Delta variant shows evidence that for persons not fully vaccinated, getting a viral test one day prior to departure can reduce the risk of traveling with COVID–19 by 40%.[51] When this window is expanded to two days prior to departure, the reduction in risk is 26%, and for three days prior to departure, the risk reduction is only an estimated 14%. This modeling was based on real-world data on virus transmissibility.[52] [53] [54]

CDC's modeling also demonstrates that among travelers who are fully vaccinated with a vaccine that has 60% effectiveness against SARS–CoV–2 infection, getting tested with a NAAT or antigen test 3 days before departure can reduce risk that a person is infectious with COVID–19 during travel by 66%.[55] Among fully vaccinated travelers, if this testing window is decreased to two days, this risk is reduced by 71%, and by 76% at one day before travel. Therefore, there is little public health advantage to shortening the time period for testing for fully vaccinated air passengers.[56] The combination of vaccination and pre-travel testing provides a greater level of protection than either measure alone and is consistent with a layered strategy.

These models informed by analyses of real-world surveillance data support the requirement of this Amended Order that passengers who are not fully vaccinated get a specimen collected for a viral COVID–19 test no more than 1 day before departure to the United States to minimize the risk of transmission during travel and importing additional COVID–19 cases and possible variants into the United States. The time window between testing and travel is particularly relevant for those with longer-duration travel, such as traveling long distances or on connecting flights. However, decreasing the time window for testing before departure from three days to one day provides minimal additional public health benefit for fully vaccinated travelers. Therefore, fully vaccinated air passengers will continue to be allowed to get a specimen collected no more than 3 calendar days before their flight departure to meet the requirements of this Amended Order.

F. Proof of Being Fully Vaccinated Against COVID–19

Documentation of COVID–19 vaccination status varies globally. Governments, private industries, or medical providers may use a paper or digital certification reflecting a person's COVID–19 vaccination status that includes handwritten or typed text from an authorized healthcare care provider, pharmacy, or other qualified entity. Some governments and private industries have developed vaccination credentials that are considered ''verifiable'' because they can be electronically linked back to a person's vaccination data held by a trusted source. The trusted source is able to then confirm the authenticity and validity of the certificate and/or confirm that the vaccination took place. An example of verifiable vaccination credentials is a QR code image on paper or in digital format, such as on a mobile phone, that links to the person's verified vaccination data.

Considering the variability of vaccine credentials globally, this Amended Order provides the airline or aircraft operator the discretion to accept different forms of vaccine credentials, whether paper, digital, or verifiable, for passengers who submit a *Qualifying Test for Fully Vaccinated* accompanied by *Proof of Being Fully Vaccinated Against COVID–19.* While this Amended Order may be enforced through criminal penalties under 18 U.S.C. 3559, 3571; 42 U.S.C. 271; and 42 CFR 71.2, CDC does not intend to rely on this enforcement mechanism for airlines or aircraft operators who accept paper or digital documentation of vaccination (*i.e.,* paper or digital vaccination records, verifiable vaccination credential) from a passenger in good faith and use best efforts to fulfill the requirements of this Amended Order.

G. Statement of Good Cause Under the Administrative Procedure Act (''APA'')

COVID–19 cases, hospitalizations, and deaths rapidly increased over the summer and early fall of 2021, especially in areas with higher levels of community transmission and lower vaccination coverage.[57] Pediatric cases and hospitalizations also increased over the same time period.[58] [59] While cases are currently decreasing in the United

[49] International Travel During COVID–19 *https://www.cdc.gov/coronavirus/2019-ncov/travelers/international-travel-during-covid19.html.*

[50] *https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.*

[51] Public Health Guidance for Potential COVID–19 Exposure Associated with Travel *https://www.cdc.gov/coronavirus/2019-ncov/php/risk-assessment.html.*

[52] He, X., Lau, E.H.Y., Wu, P. et al. Temporal dynamics in viral shedding and transmissibility of COVID–19. Nat Med 26, 672–675 (2020). *https://doi.org/10.1038/s41591-020-0869-5.*

[53] Wölfel, R., Corman, V.M., Guggemos, W. et al. Virological assessment of hospitalized patients with COVID–2019. Nature 581, 465–469 (2020). *https://doi.org/10.1038/s41586-020-2196-x.*

[54] Rachael Pung, Tze Minn Mak, Adam J Kucharski, Vernon J Lee, Serial intervals in SARS–CoV–2 B.1.617.2 variant cases, The Lancet, 2021 ISSN 0140–6736, *https://doi.org/10.1016/S0140-6736(21)01697-4.*

[55] Public Health Guidance for Potential COVID–19 Exposure Associated with Travel *https://www.cdc.gov/coronavirus/2019-ncov/php/risk-assessment.html.*

[56] CDC recommends that fully vaccinated cruise ship passengers receive a COVID–19 PCR or rapid antigen test no more than 2 days before boarding or on embarkation day. See *https://www.cdc.gov/quarantine/cruise/covid19-operations-manual-cso.html.* While cruise ships share similarities with other forms of travel, including air travel, cruise ships represent a unique environment that facilitates the spread of COVID–19 based on such factors as their larger size, with larger cruises of more than 6,000 passengers, and ability to bring an international cohort of passengers and crew together for days or weeks at a time through frequent events such as group and buffet dining, entertainment events, and excursions. Accordingly, testing, and other public health recommendations for cruise ships and air travel may differ.

[57] Scobie HM, Johnson AG, Suthar AB, Severson R, Alden NB, Balter S, Bertolino D, Blythe D, Brady S, Cadwell B, Cheng I. Monitoring incidence of covid–19 cases, hospitalizations, and deaths, by vaccination status—13 US jurisdictions, April 4–July 17, 2021. Morbidity and Mortality Weekly Report. 2021 Sep 17;70(37):1284.

[58] Delahoy MJ, Ujamaa D, Whitaker M, O'Halloran A, Anglin O, Burns E, Cummings C, Holstein R, Kambhampati AK, Milucky J, Patel K. Hospitalizations associated with COVID–19 among children and adolescents—COVID–NET, 14 states, March 1, 2020–August 14, 2021. Morbidity and Mortality Weekly Report. 2021 Sep 10;70(36):1255.

[59] Siegel DA, Reses HE, Cool AJ et al. Trends in COVID–19 cases, emergency department visits, and hospital admissions among children and adolescents aged 0–17 years—United States, August 2020–August 2021. Morbidity and Mortality Weekly Report. 2021 Sep 10;70(36):1249.

States, during the entirety of this pandemic, cases have tended to surge in waves, including after high-volume travel periods, with 4 waves as of October 2021.[18] Therefore, additional surges of cases and deaths are very possible.

To reduce introduction and spread of future SARS–CoV–2 variants into the United States at a time when global air travel is increasing, CDC must take quick and targeted action to curtail the introduction of other new variants into the United States.

This Amended Order is not a rule within the meaning of the Administrative Procedure Act (''APA'') but rather is an emergency action taken under the existing authority of 42 U.S.C. 264(a) and 42 CFR 71.20 and 71.31(b), which were promulgated in accordance with the APA after full notice and comment rulemaking and a delay in effective date. In the event that this Amended Order qualifies as a new rule under the APA, notice and comment and a delay in effective date are not required because there is good cause to dispense with prior public notice and comment and a delay in effective date. *See* 5 U.S.C. 553(b)(B), (d)(3).

Considering the rapid and unpredictable developments in the public health emergency caused by COVID–19, it would be impracticable and contrary to the public's health, and by extension the public's interest, to delay the issuance and effective date of this Amended Order. Further delay could increase risk of transmission and importation of additional undetected cases of SARS–CoV–2 Delta variant or other emerging variants through not fully vaccinated passengers who become infectious during the 3-day window currently allowed for predeparture testing.

Similarly, the Office of Information and Regulatory Affairs has determined that if this Amended Order were a rule, it would be a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (the Congressional Review Act), 5 U.S.C. 804(2), but there would not be a delay in its effective date as the agency has determined that there would be good cause to make the requirements herein effective immediately under the APA, 5 U.S.C. 808(2).

This Amended Order is also an economically significant regulatory action under Executive Order 12866 and has therefore been reviewed by the Office of Information and Regulatory Affairs of the Office of Management and Budget.

If any provision of this Amended Order, or the application of any provision to any carriers, persons, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any carriers, persons, or circumstances other than those to which it is held invalid, shall remain valid and in effect.

Pursuant to 5 U.S.C. 553(b)(B), and for the reasons stated above, I hereby conclude that notice-and-comment rulemaking would defeat the purpose of the Amended Order and endanger the public health, and is, therefore, impracticable and contrary to the public interest. For the same reasons, I have determined, consistent with 5 U.S.C. 553(d)(3), that there is good cause to make this Amended Order effective immediately upon filing at the Office of the Federal Register.

Action

For the reasons outlined above, I hereby determine that passengers covered by this Amended Order are at risk of transmitting SARS–CoV–2 virus, including virus variants, and that requiring such passengers to demonstrate either negative COVID–19 test results or recovery from COVID–19 after previous SARS–CoV–2 infection is needed as a public health measure to protect the health of fellow travelers and U.S. communities. These actions are necessary to reduce the risk of transmission of new SARS–CoV–2 virus, including virus variants, and to protect the health of fellow travelers and U.S. communities.

This Amended Order shall remain effective until either the expiration of the Secretary of HHS' declaration that COVID–19 constitutes a public health emergency, or I determine that based on specific public health or other considerations that continuation of this Order is no longer necessary to prevent the further introduction, transmission, and spread of COVID–19 into the United States, whichever occurs first. Upon determining that continuation of this Order is no longer necessary to prevent the further introduction, transmission, and spread of COVID–19 into the United States, I will publish a notice in the **Federal Register** terminating this Order. I retain the authority to modify or terminate the Order, or its implementation, at any time as needed to protect public health.

1. Requirements for Airlines & Other Aircraft Operators

Any airline or other aircraft operator with passengers arriving into the United States from a foreign country, shall:

A. Confirm that every passenger—2 years or older—onboard the aircraft has paper or digital documentation reflecting a *Qualifying Test for Fully Vaccinated,* a *Qualifying Test for Not Fully Vaccinated,* or *Documentation of Recovery.*

(1) Requirements for a *Qualifying Test for Fully Vaccinated* include:

a. Documentation of a negative SARS–CoV–2 viral test result from a specimen collected no more than 3 calendar days preceding the passenger's flight to the United States. The negative SARS–CoV–2 viral test result should include:

i. Personal identifiers (*e.g.,* name and date of birth) on the negative test result that match the personal identifiers on the passenger's passport or other travel documents;

ii. a specimen collection date indicating that the specimen was collected no more than 3 days before the flight's departure (or first flight in a series of connections booked on the same itinerary);[60]

iii. type of viral test indicating it is a NAAT or antigen test;

iv. a test result that states ''NEGATIVE,'' ''SARS–CoV–2 RNA NOT DETECTED,'' ''SARS–CoV–2 ANTIGEN NOT DETECTED,'' or ''COVID–19 NOT DETECTED,'' or other indication that SARS–CoV–2 was not detected in the individual's specimen. A test marked ''invalid'' is not acceptable; and

v. information about the entity issuing the result (*e.g.,* laboratory, healthcare entity, or telehealth service), such as the name and contact information; and

b. *Proof of Being Fully Vaccinated Against COVID–19* against COVID–19 as defined in this Amended Order, that includes personal identifiers (*e.g.,* name and date of birth) that match the personal identifiers on the passenger's passport or other travel documents.

(2) Requirements for a *Qualifying Test for Not Fully Vaccinated* include:

a. Documentation of a negative SARS–CoV–2 viral test result from a specimen collected no more than 1 day preceding the passenger's flight to the United States. The negative SARS–CoV–2 viral test result should include:

i. Personal identifiers (*e.g.,* name and date of birth) on the negative test result that match the personal identifiers on the passenger's passport or other travel documents;

ii. specimen collection date indicating that the specimen was collected no more than 1 day before the flight's departure (or first flight in a series of

[60] Passengers traveling on a series of connections booked on the same itinerary also have the option of obtaining the required negative test result en route to the United States if testing within the required time frame is not available at their point of origin.

connections booked on the same itinerary);[61]

iii. type of viral test indicating it is a NAAT or antigen test;

iv. a test result that states ''NEGATIVE,'' ''SARS–CoV–2 RNA NOT DETECTED,'' ''SARS–CoV–2 ANTIGEN NOT DETECTED,'' or ''COVID–19 NOT DETECTED,'' or other indication that SARS–CoV–2 was not detected in the individual's specimen. A test marked ''invalid'' is not acceptable; and

v. information about the entity issuing the result (*e.g.,* laboratory, healthcare entity, or telehealth service), such as the name and contact information.

(3) Requirements for *Documentation of Recovery* include:

a. Documentation of a positive SARS–CoV–2 viral test result from a specimen collected no more than three months (90 calendar days) preceding the passenger's flight to the United States, or at such other intervals as specified in CDC guidance. [62] The positive SARS–CoV–2 viral test result should include:

i. Personal identifiers (*e.g.,* name and date of birth) on the positive test result match the personal identifiers on the passenger's passport or other travel documents;

ii. a specimen collection date indicating that the specimen was collected no more than 90 calendar days before the flight's departure;

iii. information that the test performed was a viral test indicating it is a NAAT or antigen test;

iv. a test result that states ''POSITIVE,'' ''SARS–CoV–2 RNA DETECTED,'' ''SARS–CoV–2 ANTIGEN DETECTED,'' or ''COVID–19 DETECTED,'' or other indication that SARS–CoV–2 was detected in the individual's specimen. A test marked ''invalid'' is not acceptable; and

v. information about the entity issuing the result (*e.g.,* laboratory, healthcare entity, or telehealth service), such as the name and contact information.

b. A signed letter from a licensed healthcare provider or a public health official stating that the passenger has been cleared for travel.[63] [64] The letter must have personal identifiers (*e.g.,* name and date of birth) that match the personal identifiers on the passenger's passport or other travel documents. The letter must be signed and dated on official letterhead that contains the name, address, and phone number of the healthcare provider or public health official who signed the letter.

B. Confirm that each passenger has attested to having received a negative result for a *Qualifying Test for Fully Vaccinated* plus being fully vaccinated, a negative result for a *Qualifying Test for Not Fully Vaccinated,* or having tested positive for SARS–CoV–2 on a specimen collected no more than 90 calendar days before the flight and been cleared to travel. Airlines or other aircraft operators must retain a copy of each passenger attestation for 2 years. The attestation is attached to this order as Attachment A.

C. Not board any passenger without confirming the documentation as set forth in A and B.

Any airline or other aircraft operator that fails to comply with section 1, ''Requirements for Airlines & Other Aircraft Operators,'' may be subject to criminal penalties under, *inter alia,* 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571. However, CDC does not intend to rely on this enforcement mechanism for airlines or aircraft operators who accept paper or digital documentation of vaccination (*i.e.,* paper or digital vaccination records, or verifiable vaccination credential) from a passenger in good faith and use best efforts to fulfill the requirements of this Amended Order.

2. Requirements for Aircraft Passengers

Any aircraft passenger [65] [66] departing from any foreign country with a destination in the United States shall—

A. Present paper or digital documentation reflecting one of the following:

(1) A negative *Qualifying Test for Fully Vaccinated* that has a specimen collection date indicating that the specimen was collected no more than 3 calendar days before the flight's departure (or first flight in a series of connections booked on the same itinerary) [67] plus *Proof of Being Fully Vaccinated Against COVID–19* against COVID–19;

(2) A negative *Qualifying Test for Not Fully Vaccinated* that has a specimen collection date indicating that the specimen was collected no more than 1 day before the flight's departure (or first flight in a series of connections booked on the same itinerary); [68] or

(3) *Documentation of Recovery* from COVID–19 that includes a positive SARS–CoV–2 viral test result conducted on a specimen collected no more than 90 calendar days before the flight and a letter from a licensed healthcare provider or public health official stating that the passenger has been cleared for travel.[69] [70]

B. Provide the attestation to the airline or other aircraft operator, of one of the following:

(1) having received a negative result for the *Qualifying Test for Vaccinated* and being fully vaccinated against COVID–19;

(2) having received a negative result for the *Qualifying Test for Not Fully Vaccinated;* or

(3) having tested positive for SARS-CoV–2 on a specimen collected no more than 90 calendar days before the flight and been cleared to travel.

The attestation is attached to this order as Attachment A. Unless otherwise permitted by law, a parent or other authorized individual may present the required documentation on behalf of a passenger 2–17 years of age. An authorized individual may act on behalf of any passenger who is unable to act on their own behalf (*e.g.,* by reason of age, or physical or mental impairment).

C. Retain a copy of the applicable documentation listed in part A of this section and produce such

[61] *Ibid.*

[62] Interim Guidance on Ending Isolation and Precautions for Adults with COVID–19 *https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.*

[63] Healthcare providers and public health officials should follow CDC guidance in clearing patients for travel to the United States. Applicable guidance is available at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html.*

[64] A letter from a healthcare provider or a public health official that clears the person to end isolation, *e.g.,* to return to work or school, can also be used to show that the person has been cleared to travel, even if travel is not specifically mentioned in the letter.

[65] A parent or other authorized individual may present the required documentation on behalf of a passenger 2–17 years of age. An authorized individual may act on behalf of any passenger who is unable to act on their own behalf (*e.g.,* by reason of age, or physical or mental impairment).

[66] Children between the ages of 2 and 17 who are not fully vaccinated may board a flight to the United States with a negative pre-departure COVID–19 viral test conducted on a specimen collected no more than 3 calendar days before departure (*i.e.,* Qualifying Test for Fully Vaccinated) if traveling accompanied by fully vaccinated parents or guardians. If traveling unaccompanied or if one or more of the parents or guardians accompanying the child is not fully vaccinated, the child must present a negative pre-departure COVID–19 viral test on a specimen collected no more than 1 day before departure (*i.e.,* a Qualifying Test for Not Fully Vaccinated).

[67] Passengers traveling on a series of connections booked on the same itinerary also have the option of obtaining the required negative test result en route to the United States if testing within the required time frame is not available at their point of origin.

[68] *Ibid.*

[69] A letter from a healthcare provider or a public health official that clears the person to end isolation, *e.g.,* to return to work or school, can also be used to show that the person has been cleared to travel, even if travel is not specifically mentioned in the letter.

[70] Healthcare providers and public health officials should follow CDC guidance in clearing patients for travel to the United States. Applicable guidance is available at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html.*

documentation upon request to any U.S. government official or a cooperating state or local public health authority after arrival in the United States.

Any passenger who fails to comply with the requirements of section 2, ''Requirements for Aircraft Passengers,'' may be subject to criminal penalties under, *inter alia,* 42 U.S.C. 271 and 42 CFR 71.2, in conjunction with 18 U.S.C. 3559 and 3571. Willfully giving false or misleading information to the government may result in criminal penalties under, *inter alia,* 18 U.S.C. 1001.

This Amended Order shall be enforceable through the provisions of 18 U.S.C. 3559, 3571; 42 U.S.C. 243, 268, 271; and 42 CFR 71.2.

As the pandemic continues to rapidly evolve and more scientific data becomes available regarding additional variants of concern and/or the effectiveness of COVID–19 vaccines, CDC may exercise its enforcement discretion to broaden the scope of accepted vaccines or combinations of accepted vaccines to allow passengers and airline and aircraft operators greater flexibility regarding the requirements of this Amended Order or to align with current CDC guidance. Such exercises of enforcement discretion will be announced on CDC's website and the Amended Order will be further amended as soon as practicable through an updated publication in the **Federal Register**.

Effective Date

This Amended Order shall enter into effect at 12:01am EST (5:01am GMT) on November 8, 2021, and will remain in effect unless modified or rescinded based on specific public health or other considerations, or until the Secretary of Health and Human Services rescinds the determination under section 319 of the Public Health Service Act (42 U.S.C. 247d) that a public health emergency exists with respect to COVID–19.

BILLING CODE 4163–18–P

Form OMB Control No: XXXX-XXXX
Expiration date: XX/XX/XXXX[71]

ATTACHMENT A: COMBINED PASSENGER DISCLOSURE AND ATTESTATION TO THE UNITED STATES OF AMERICA

This combined passenger disclosure and attestation fulfills the requirements of U.S. Centers for Disease Control and Prevention (CDC) Orders: *Requirement for Proof of Negative COVID-19 Test Result or Recovery from COVID-19 for All Airline Passengers Arriving into the United States* and *Order Implementing Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID-19 Pandemic.*[72] As directed by the CDC and the Transportation Security Administration (TSA), including through a forthcoming Security Directive, to be issued after consultation with CDC, and consistent with CDC's Order implementing the Presidential

[71] Public reporting burden of this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. 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. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA XXXX-XXXX

[72] These requirements (e.g. proof of negative COVID-10 test result and proof of being fully vaccinated against COVID-19)do not apply to crew members of airlines or other aircraft operators if they are traveling for the purpose of operating the aircraft, or repositioning (i.e., on "deadhead" status), provided their assignment is under an air carrier's or operator's occupational health and safety program that follows applicable industry standard protocols for the prevention of COVID-19 as set forth in relevant Safety Alerts for Operators (SAFOs) issued by the Federal Aviation Administration (FAA).

Proclamation, all airline or other aircraft operators must provide the following disclosures to all passengers prior to their boarding a flight from a foreign country to the United States.

The information provided below must be accurate and complete to the best of the individual's knowledge. Under United States federal law, each passenger must complete the applicable portion of the attestation and provide it to the airline or aircraft operator prior to boarding a flight to the United States from a foreign country. Failure to complete and present the applicable portion of the attestation or submitting false or misleading information, could result in delay of travel, denial of boarding, denial of boarding on future travel, or put the passenger or other individuals at risk of harm, including serious bodily injury or death. Any passenger who fails to comply with these requirements may be subject to criminal penalties. Willfully providing false or misleading information may lead to criminal fines and imprisonment under, among others, 18 U.S.C. § 1001. Providing this information can help protect you, your friends and family, your communities, and the United States. CDC appreciates your cooperation.

AIRLINE AND AIRCRAFT OPERATOR DISCLOSURE REQUIREMENTS:

As required by United States federal law, all airlines or other aircraft operators must collect the passenger attestation on behalf of the U.S. Government.

All airlines and other aircraft operators must additionally confirm one of the following for each passenger – 2 years and older--prior to their boarding a flight to the United States from a foreign country:

1. A negative result for a *Qualifying Test for Fully Vaccinated* for those passengers who provide proof of being fully vaccinated,
2. A negative result for a *Qualifying Test for Not Fully Vaccinated*, or
3. Documentation of recovery from COVID-19 in the form of a positive COVID-19 viral test on a sample taken no more than 90 days prior to departure and clearance to travel.

As directed by the TSA, including through a forthcoming security directive, all airlines and other aircraft operators must additionally confirm one of the following for each noncitizen who is a nonimmigrant passenger prior to their boarding a flight to the United States from a foreign country:

1. Proof of being *Fully Vaccinated Against COVID-19*
2. Proof of being excepted from the requirement to be *Fully Vaccinated Against COVID-19*.

SECTION 1:

Passenger Attestation Requirement Relating to Proof of Negative COVID-19 Test Result or Recovery from COVID-19

TO BE COMPLETED BY ALL PASSENGERS:

1. [ ] I attest that I am fully vaccinated against COVID-19 and have received a **negative** pre-departure test result for COVID-19. The test was a viral test that was conducted on a specimen collected from me no more than **3 days** before this flight's departure.

   [ ] On behalf of [_____], I attest that this person is fully vaccinated against COVID-19 and received a **negative** pre-departure test result for COVID-19. The test was a viral test that was conducted on a specimen collected from the person no more than **3 days** before the flight's departure.

2. [ ] I attest that I am **not** fully vaccinated against COVID-19 and have received a **negative** pre-departure test result for COVID-19. The test was a viral test that was conducted on a specimen collected from me no more than **1 day** before the flight's departure.

   [ ] On behalf of [_____], I attest that this person is **not** fully vaccinated against COVID-19 and has received a **negative** pre-departure test result for

COVID-19. The test was a viral test that was conducted on a specimen collected from the person no more than **1 day** before the flight's departure.

3. [ ] I attest that I tested positive for COVID-19 and **have been cleared for travel** by a licensed healthcare provider or public health official. The test was a viral test that was conducted on a specimen collected from me no more than 90 days before the flight's departure.

[ ] On behalf of [_____], I attest that this person tested positive for COVID-19 and **has been cleared for travel** by a licensed healthcare provider or public health official. The test was a viral test that was conducted on a specimen collected from the person no more than 90 days before the flight's departure.

4. [ ] On behalf of [_____], I attest that this person is between 2 and 17 years of age, is not fully vaccinated against COVID-19, and received a **negative** pre-departure test result for COVID-19. The test was a viral test that was conducted on a specimen collected from the person no more than **3 days** before the flight's departure and this person is traveling with a fully vaccinated parent(s) or guardian(s).

5. [ ] I attest that I have received a humanitarian or emergency exemption to the testing requirement or the documentation of recovery, as determined by CDC and documented by an official U.S. Government letter.

[ ] On behalf of [_____], I attest that this person has received a humanitarian or emergency exemption to the testing requirement or the documentation of recovery, as determined by CDC and documented by an official U.S. Government letter.

SECTION 2:

Passenger Attestation Requirement Relating to Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID-19 Pandemic

TO BE COMPLETED BY EVERY COVERED INDIVIDUAL:[73]

1. [ ] I attest that I am **fully vaccinated** against COVID-19 (*sign the form to complete the Attestation*).

   [ ] On behalf of [_____], I attest that this person is fully vaccinated against COVID-19 (*sign the form to complete the Attestation*).

2. [ ] I am **not fully vaccinated** and attest that I am **excepted** from the requirement to present *Proof of Being Fully Vaccinated Against COVID-19* based on one of the following *(check only one box, as applicable)*:

   ☐ Diplomatic and Official Foreign Government Travel (*complete sections 3 and 5, unless as determined by CDC, these requirements cannot be completed consistent with the purposes of the official government travel, and sign the form to complete the Attestation*).

[73] This means any passenger covered by the Proclamation and this Order: a noncitizen (other than a U.S. lawful permanent resident or U.S. national) who is a nonimmigrant seeking to enter the United States by air travel. This term does not apply to crew members of airlines or other aircraft operators if such crewmembers and operators adhere to all industry standard protocols for the prevention of COVID-19, as set forth in relevant guidance for crewmember health issued by the CDC or by the Federal Aviation Administration in coordination with the CDC.

- ☐ Child under 18 years of age (*complete section 4 and sign the form to complete the Attestation OR have parent/legal guardian complete section 4 and sign on behalf of a person under 18 years of age).*
- ☐ Participant in certain COVID-19 vaccine trials as determined by CDC (*complete section 4 and sign the form to complete the Attestation).*
- ☐ Medical contraindication to an accepted COVID-19 vaccine as determined by CDC (*complete section 3 and sign the form below to complete the Attestation).*
- ☐ Humanitarian or emergency exception as determined by CDC and documented by an official U.S. Government letter (*complete sections 3 and 5 below and sign the form to complete the Attestation).*
- ☐ Valid nonimmigrant visa holder (excluding B-1 or B-2 visas) and citizen of a *Foreign Country with Limited COVID-19 Vaccine Availability* as determined by CDC (*complete sections 3 and 5 below and sign the form to complete the Attestation).*
- ☐ Member of the U.S. Armed Forces or spouse or child (under 18 years of age) of a member of the U.S. Armed Forces (*sign the form to complete the Attestation*).
- ☐ Sea crew member traveling pursuant to a C-1 and D nonimmigrant visa (*complete sections 3 and 5 below and sign the form to complete the Attestation).*

☐ Person whose entry is in the U.S. national interest as determined by the Secretary of State, the Secretary of Transportation, the Secretary of Homeland Security, or their designees (*complete sections 3 and 5 below and sign the form to complete the Attestation).*

[ ] On behalf of [_____], I attest that this person is **excepted** from the requirement to present *Proof of Being Fully Vaccinated Against COVID-19* based on one of the following *(check only one box, as applicable)*:

☐ Diplomatic and Official Foreign Government Travel (*complete sections 3 and 5, unless as determined by CDC, these requirements cannot be completed consistent with the purposes of the official government travel, and sign the form to complete the Attestation*).

☐ Child under 18 years of age (*complete section 4 and sign the form to complete the Attestation).*

☐ Participant in certain COVID-19 vaccine trials as determined by CDC (*complete section 4 and sign the form to complete the Attestation).*

☐ Medical contraindication to an accepted COVID-19 vaccine as determined by CDC (*complete section 3 and sign the form below to complete the Attestation).*

☐ Humanitarian and emergency exception as determined by CDC and documented by an official U.S. Government letter

(*complete sections 3 and 5 below and sign the form to complete the Attestation*).

☐ Valid nonimmigrant visa holder (excluding B-1 or B-2 visas) and citizen of a *Foreign Country with Limited COVID-19 Vaccine Availability* as determined by CDC (*complete sections 3 and 5 below and sign the form to complete the Attestation*).

☐ Member of the U.S. Armed Forces or spouse or child (under 18 years of age) of a member of the U.S. Armed Forces (*sign the form to complete the Attestation*).

☐ Sea crew member traveling pursuant to a C-1 and D nonimmigrant visa (*complete sections 3 and 5 below and sign the form to complete the Attestation*).

☐ Person whose entry is in the U.S. national interest as determined by the Secretary of State, the Secretary of Transportation, the Secretary of Homeland Security, or their designees (*complete sections 3 and 5 below and sign the form to complete the Attestation*).

3. [ ] I attest that I have made the following arrangements (*must check all boxes*).

☐ To be tested with a COVID-19 viral test 3-5 days after arriving in the United States, unless I have documentation of having recovered from COVID-19 in the past 90 days;

- ☐ To self-quarantine for a full 7 days, even if the test result to my post-arrival viral test is negative, unless I have documentation of having recovered from COVID-19 in the past 90 days; and
- ☐ To self-isolate if the result of the post-arrival viral test is positive or if I develop COVID-19 symptoms.

[ ] On behalf of [_____], I attest that such person is **excepted** from the requirement to present *Proof of Being Fully Vaccinated Against COVID-19* and has made or has had the following arrangements made on their behalf (*must check all boxes*).

- ☐ Testing with a COVID-19 viral test 3-5 days after arriving in the United States, unless such person has documentation of having recovered from COVID-19 in the past 90 days;
- ☐ Self-quarantine for a full 7 days, even if the test result to the person's post-arrival viral test is negative, unless such person has documentation of having recovered from COVID-19 in the past 90 days; and
- ☐ Self-isolation if the result of the person's post-arrival viral test is positive or if the person develops COVID-19 symptoms.

4. [ ] I attest that I have made the following arrangements (*must check all boxes*).

☐ To be tested with a COVID-19 viral test 3-5 days after arriving in the United States, unless I have documentation of having recovered from COVID-19 in the past 90 days; and

☐ To self-isolate if the result of the post-arrival viral test is positive or if I develop COVID-19 symptoms.

[ ] On behalf of [_____], I attest that such person is **excepted** from the requirement to present *Proof of Being Fully Vaccinated Against COVID-19* and has made or has had the following arrangements made on their behalf (*must check all boxes*).

☐ Testing with a COVID-19 viral test 3-5 days after arriving in the United States, unless such person has documentation of having recovered from COVID-19 in the past 90 days; and

☐ Self-isolation if the result of the person's post-arrival viral test is positive or if the person develops COVID-19 symptoms.

5. Do you, or the person you are attesting on behalf of, intend to stay in the United States for more than 60 days?

☐ YES (*complete statement below and then sign form*)

☐ NO *(skip statement below and sign form)*

[ ] If YES, I attest that I agree to be vaccinated and have arranged to become fully vaccinated against COVID-19 within 60 days of arriving in the United States, or as soon thereafter as is medically appropriate.

[ ] If YES, on behalf of [_____], I attest that such person agrees to be vaccinated and has arranged to become fully vaccinated against COVID-19 within 60 days of arriving in the United States, or as soon as thereafter as is medically appropriate.

_____ Print Name

_____ Signature

_____Date

Privacy Act Statement for Travelers Relating to the Requirement to Provide Proof of a Negative COVID-19 Test Result

The United States Centers for Disease Control and Prevention (CDC) requires airlines and other aircraft operators to collect this information pursuant to 42 C.F.R. §§ 71.20 and 71.31(b), as authorized by 42 U.S.C. § 264. Providing this information is mandatory for all passengers arriving by aircraft into the United States. Failure to provide this information may prevent you from boarding the plane. Additionally, passengers will be required to attest to providing complete and accurate information, and failure to do so may lead to other consequences, including criminal penalties. CDC will use this information to help prevent the introduction, transmission, and spread of communicable diseases by performing contact tracing investigations and notifying exposed individuals and public health authorities; and for health education, treatment, prophylaxis, or other appropriate public health interventions, including the implementation of travel restrictions.

The Privacy Act of 1974, 5 U.S.C. § 552a, governs the collection and use of this information. The information maintained by CDC will be covered by CDC's System of Records No. 09-20-0171, Quarantine- and Traveler-Related Activities,

Including Records for Contact Tracing Investigation and Notification under 42 C.F.R. Parts 70 and 71. See 72 Fed. Reg. 70867 (Dec. 13, 2007), as amended by 76 Fed. Reg. 4485 (Jan. 25, 2011) and 83 Fed. Reg. 6591 (Feb. 14, 2018). CDC will only disclose information from the system outside the CDC and the U.S. Department of Health and Human Services as the Privacy Act permits, including in accordance with the routine uses published for this system in the Federal Register, and as authorized by law. Such lawful purposes may include, but are not limited to, sharing identifiable information with state and local public health departments, and other cooperating authorities. CDC and cooperating authorities will retain, use, delete, or otherwise destroy the designated information in accordance with federal law and the System of Records Notice (SORN) set forth above. You may contact the system manager at dgmqpolicyoffice@cdc.gov or by mailing Policy Office, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16-4, Atlanta, GA 30329, if you have questions about CDC's use of your data.

Authority

The authority for these orders is Sections 361 and 365 of the Public Health Service Act (42 U.S.C. 264) and 42 CFR 71.20 & 71.31(b).

Sherri Berger,

Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2021–24388 Filed 11–3–21; 4:15 pm]

BILLING CODE 4163–18–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #0970–0529]

Proposed Information Collection Activity; Prevention Services Data Collection

AGENCY: Children's Bureau, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), Children's Bureau is requesting a 3-year extension of the Prevention Services Data Collection (OMB #0970–0529, expiration 7/31/2022). There are no changes requested to the form.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Section 471(e)(4)(E) of the Social Security Act (the Act) (42 U.S.C. 671), as amended by Public Law 115–123, requires state and tribal child welfare agencies to collect and report to ACF information on children receiving prevention and family services and programs. Title IV–E Agencies must report the following:

- The specific services or programs provided.
- The total expenditures for each of the services or programs provided.
- The duration of the services or programs provided, and
- If the child was identified in a prevention plan as a candidate for foster care:
  - The child's placement status at the beginning, and at the end, of the 12-month period that begins on the date the child was identified as a candidate for foster care in a prevention plan; and
  - Whether the child entered foster care during the initial 12-month period and during the subsequent 12-month period.

To date, approximately ¾ of the Title IV–E Agencies have chosen to provide these prevention services; however, it is believed that this number will continue to increase over time as states voluntarily opt-in to the program in order to utilize IV–E funding to provide prevention programs and services to children and families.

The data collected will continue to inform federal policy decisions, program management, and responses to Congressional and Departmental inquiries. Specifically, the data will provide information about the use and availability of prevention services to children to prevent the need for foster care placement. The data contains personally identifiable information (date of birth and race/ethnicity).

Respondents: Title IV–E Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Prevention Services Data Collection	55	2	31	3,410	1,137

Estimated Total Annual Burden Hours: 1,137.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 471(e)(4)(E) of the Act (42 U.S.C. 671), as amended by Public Law 115–123.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–24224 Filed 11–4–21; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Request for Certification of Adult Victims of Human Trafficking

AGENCY: Office on Trafficking in Persons, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), Office on Trafficking in Persons (OTIP), is requesting a 3-year extension of the Request for Certification of Adult Victims of Human Trafficking (RFC) form (Office of Management and Budget (OMB) #: 0970–0454, expiration 2/28/22). Minor revisions have been made to the form, including the addition of a few fields that will enable OTIP to be more responsive to congressional inquiries, federal reporting requirements, and the needs of victims.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The U.S. Department of Health and Human Services (HHS) provides letters of certification to foreign national victims of severe forms of trafficking in persons under the authority of the Trafficking Victims Protection Act of 2000 (TVPA), as amended 22 U.S.C. Section 7105(b)(1)(C) and (E). HHS delegated this authority to OTIP. Certification is required for foreign national adult victims of human trafficking in the United States to apply for federally funded benefits and services.

OTIP developed a form for potential victims and their advocates, including case managers, attorneys, law enforcement officers, service providers, and other representatives to provide the required information for certification to HHS in accordance with the TVPA of 2000, as amended. The RFC form (formerly titled Trafficking Victims Tracking System) was renamed in order to create continuity between the RFC and Request for Assistance for Child Victims of Human Trafficking (RFA) forms (OMB Control Number 0970–0362).

Since the RFC form originally received clearance, OTIP modernized its request process and launched Shepherd, an online case management system, to process requests for certification and assistance on behalf of foreign national adult and minor victims of trafficking. The PDF version of the form should only be used in exceptional circumstances when the online case management system is inaccessible. If a requester encounters issues submitting a request through Shepherd, they may submit the RFC form to OTIP as a password protected PDF to *Trafficking@acf.hhs.gov.* The form asks the requester for their identifying information, identifying information for the foreign national adult in the event the form is submitted by a case manager, and information describing the victim's case management service needs. The minor revisions made to this form enable OTIP to better fulfill its mandate in accordance with the TVPA of 2000, as amended. These revisions also enable OTIP to be more responsive to congressional inquiries, federal reporting requirements, and the needs of victims, as the information provided will be factored into policy and program development efforts.

Respondents: Potential victims of a severe form of trafficking in persons and their advocates, including case managers, attorneys, law enforcement officers, service providers, and other representatives.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Request for Certification of Adult Victims of Human Trafficking	1,300	1	1	1,300	433

Estimated Total Annual Burden Hours: 433.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 22 U.S.C. 7105.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–24233 Filed 11–4–21; 8:45 am]

BILLING CODE 4184–47–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0515]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarketing Adverse Experience Reporting and Recordkeeping for Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 6, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0230. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Postmarketing Adverse Experience Reporting and Recordkeeping for Drug and Biologics Products

OMB Control Number 0910–0230—Revision

This information collection supports statutory provisions set forth in the Federal Food, Drug, and Cosmetic Act (FD&C Act) regarding the monitoring of FDA-regulated products. Specifically,

FDA must be promptly informed of adverse experiences associated with the use of marketed drugs, including human drugs and biological products. Regulations in §§ 310.305 and 314.80 (21 CFR 310.305 and 314.80) implement reporting and recordkeeping requirements that enable FDA to take action to protect the public health from adverse drug experiences. All applicants who have received marketing approval for drug products are required to report serious, unexpected adverse drug experiences (15-day ''Alert reports''), as well as followup reports (§ 314.80(c)(1)) to FDA. This includes reports of all foreign or domestic adverse experiences as well as those based on information from applicable scientific literature and certain reports from postmarketing studies. Section 314.80(c)(1)(iii) pertains to such reports submitted by nonapplicants.

Under § 314.80(c)(2), applicants must provide periodic reports of adverse drug experiences. For the reporting interval, a periodic report includes reports of serious, expected adverse drug experiences, all nonserious adverse drug experiences, and an index of these reports; a narrative summary and analysis of adverse drug experiences; an analysis of the 15-day Alert reports submitted during the reporting interval; and a history of actions taken because of adverse drug experiences. Under § 314.80(j), applicants must keep for 10 years records of all adverse drug experience reports known to the applicant.

For marketed prescription drug products without approved new drug applications (NDAs) or abbreviated new drug applications (ANDAs), manufacturers, packers, and distributors are required to report to FDA serious, unexpected adverse drug experiences as well as followup reports (§ 310.305(c)). Section 310.305(c)(5) pertains to the submission of followup reports to reports forwarded to the manufacturers, packers, and distributors by FDA. Under § 310.305(g), each manufacturer, packer, and distributor shall maintain for 10 years records of all adverse drug experiences required to be reported.

Section 760 of the FD&C Act (21 U.S.C. 379aa) also provides for mandatory safety reporting for over-the-counter (OTC) human drug products not subject to applications approved under section 505 of the FD&C Act (21 U.S.C. 355) (NDAs or ANDAs). These requirements apply to all OTC drug products marketed without an approved application, including those marketed under the OTC Drug Monograph Review process (whether or not subject to a final monograph), those marketed outside the monograph system, and including those that have been discontinued from marketing but for which a report of an adverse event was received. Under 21 CFR 329.100, respondents must submit reports according to section 760 of the FD&C Act in an electronic format.

To assist respondents with implementation of section 760 of the FD&C Act, FDA developed the guidance for industry entitled ''Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application,'' available at *https://www.fda.gov/media/77193/download.* The guidance document discusses what should be included in a serious adverse drug event report submitted under section 760(b)(1) of the FD&C Act, including how to submit these reports and followup reports under section 760(c)(2) of the FD&C Act.

Section 760(e) of the FD&C Act also requires that responsible persons maintain records of nonprescription drug adverse event reports, whether the event is serious or not, for a period of 6 years. FDA's guidance recommends that respondents maintain records of efforts to obtain the minimum data elements for a report of a serious adverse drug event and any followup reports.

The primary purpose of FDA's adverse drug experience reporting system is to enable identification of signals for potentially serious safety problems with marketed drugs. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the marketed drug provide the opportunity to collect information on rare, latent, and long-term effects. Signals are obtained from a variety of sources, including reports from patients, treating physicians, foreign regulatory agencies, and clinical investigators. Information derived from the adverse drug experience reporting system contributes directly to increased public health protection because the information enables FDA to make important changes to the product's labeling (such as adding a new warning), to make decisions about risk evaluation and mitigation strategies or the need for postmarketing studies or clinical trials and, when necessary, to initiate removal of a product from the market.

In addition, this information collection includes an International Council for Harmonisation (ICH) guidance for industry entitled ''Providing Postmarketing Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report),'' available at *https://www.fda.gov/media/85520/download.* The guidance describes the conditions under which applicants may use the ICH3 E2C(R2) Periodic Benefit-Risk Evaluation Report format for certain types of adverse event reporting. FDA regulations in §§ 314.80(c)(2) and 600.80(c)(2) (21 CFR 600.80(c)(2)) require applicants to submit postmarketing periodic safety reports for each approved application. The reports must be submitted quarterly for the first 3 years following the U.S. approval date and annually thereafter and must contain the information described in §§ 314.80(c)(2)(ii) and 600.80(c)(2)(ii) (the information collection associated with 21 CFR part 600—Biological Products, is approved under OMB control number 0910–0308). The Agency guidance assists respondents with satisfying the regulatory requirements in an alternative format, noting that the process differs depending on whether an applicable periodic safety update report (PSUR) waiver is in place. The information collection burden for waivers of a PSUR are currently approved in OMB control number 0910–0771; however, it is being consolidated with this information collection for administrative efficiency.

Similarly, the information collection accounts for burden that may be applicable to the guidance document, ''Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic,'' available at *https://www.fda.gov/media/72498/download.* In response to the Coronavirus Disease 2019 public health emergency, we revised the Agency guidance document to provide recommendations for recordkeeping applicable to any pandemic, not just influenza, including recommendations for planning, notification, and documentation for continuity of operations for firms that report postmarketing adverse events during any pandemic.

Respondents to this collection of information are: (1) Manufacturers, packers, distributors, and applicants of FDA-regulated drug and biologic products; (2) manufacturers, packers, and distributors of marketed prescription drug products without an FDA-approved application; and (3) manufacturers, packers, and distributors of marketed nonprescription drug products, including OTC drug products marketed without an approved application, OTC drug products marketed under the OTC Drug Monograph Review process (whether subject to a final monograph or not), and

drug products marketed outside the monograph system.

In the **Federal Register** of June 30, 2021 (86 FR 34759), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section or type of respondent and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
310.305(c)(5)	3	1	3	1	3
314.80(c)(1)(iii)	5	1	5	1	5
314.80(c)(2)	820	17.32	14,202	60	852,120
Reports of serious adverse drug events (§ 329.100)	285	690	196,650	6	1,179,900
Applicants that have a PSUR waiver for an approved application	55	3.4	187	1	187
Applicants that do not have a PSUR waiver for an approved application	29	2.3	67	2	134
Notifying FDA when normal reporting is not feasible	350	1	350	8	2,800
Total [2]			211,464		2,035,149

[1] The capital costs or operating and maintenance costs associated with this collection of information are approximately $25,000 annually.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section or FD&C act section and activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
310.305	25	1	25	16	400
314.80(j)	352	1,870	658,240	16	10,531,840
Recordkeeping of nonprescription drug adverse event reports (Section 760(e)(1) of the FD&C Act)	300	885.6667	265,700	8	2,125,600
Adding Adverse Event report planning to Continuity of Operations Plans	100	1	100	50	5,000
Maintaining documentation of pandemic conditions and resultant high absenteeism	350	1	350	8	2,800
Maintaining records to identify what reports have been stored and when the reporting process was restored	350	1	350	8	2,800
Total [2]			924,765		12,668,440

[1] There are no capital costs or operating costs associated with this collection of information.
[2] There are maintenance costs of approximately $22,000 annually.

We have increased our estimate to reflect expected adjustments to the information collection since our last submission for OMB review and approval.

Dated: November 1, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24236 Filed 11–4–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1996–D–0405]

Compliance Policy Guide Sec. 110.100; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the withdrawal of Compliance Policy Guide Sec. 110.100, ''Certification for Exports'' (CPG Sec. 110.100), which FDA issued in 1980. We are taking this action because CPG Sec. 110.100 contains information that is either duplicative of other information we have published or no longer reflects the Agency's current thinking.

DATES: The withdrawal is effective November 5, 2021.

FOR FURTHER INFORMATION CONTACT: Tiffany Kelley, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–348–1970, *Tiffany.Kelley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA originally issued CPG Sec. 110.100 on October 1, 1980, in the Agency's Manual of Compliance Policy Guides. The CPG was revised periodically but has not been revised since April 14, 2000.

Since FDA last revised CPG Sec. 110.100, the Agency issued separate guidance for industry on FDA export certification in 2004. FDA revised that guidance in 2005, 2019, and, most recently, in August 2021. The August 2021 version of the guidance for industry, entitled ''FDA Export Certification,'' provides the Agency's current guidance regarding FDA issuance of export certification. Persons with access to the internet may obtain the guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Although this guidance originally complemented the content in CPG Sec. 110.100, changes in the document over time have increasingly resulted in CPG Sec. 110.100 containing duplicative and outdated information. Thus, FDA is withdrawing CPG Sec. 110.100 in its entirety.

Dated: November 1, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24234 Filed 11–4–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Assistant Secretary for Administration; Delegation of Authority

Notice is hereby given that I have amended the delegation of authority to the Assistant Secretary for Preparedness and Response (ASPR); the Director, Centers for Disease Control and Prevention (CDC); the Administrator, Health Resources and Services Administration (HRSA); the Director,

National Institutes of Health (NIH); the Director, Office of Global Affairs (OGA); and the Administrator, Substance Abuse and Mental Health Services Administration (SAMHSA), specifically the authority vested in the Secretary, by section 212(l) of the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (FY19 HHS Appropriations Act) Public Law 115–245, division B, title II, (September 28, 2018), or substantially similar authorities vested in me in the future by Congress, in order to carry out international health activities, including HIV/AIDS and other infectious disease, chronic and environmental disease, and other health activities abroad. Section 212(l) of the FY19 HHS Appropriations Act permits the Secretary of HHS to exercise authority equivalent to that available to the Secretary of State under 22 U.S.C. 2669(c) to award personal services contracts for work performed in foreign countries.

The authority delegated herein includes the authority to determine the necessity of negotiating, executing, and performing such contracts without regard to statutory provisions as related to the negotiation, making, and performance of contracts and performance of work in the United States. This authority is immediately revoked in the event that any subsequent fiscal year HHS appropriations act does not contain the provision currently in section 212(1) or substantially similar authority.

The Director, CDC, may redelegate this authority to the Chief Operating Officer, CDC. This authority may not be further redelegated except as noted above.

The delegatees shall consult with the Secretary of State and relevant Chief of Mission to ensure that this authority is exercised in a manner consistent with section 207 of the Foreign Service Act of 1980 and other applicable statutes administered by the Department of State.

This amended delegation rescinds and supersedes the February 7, 2020, amended delegation concerning this authority. However, all prior redelegations of authority consistent with the content of this memorandum will remain in effect pending further redelegation.

This amended delegation became effective upon date of signature. In addition, I hereby affirm and ratify any actions taken by you or your subordinates which involved the exercise of the authorities delegated herein, or substantially similar authorities vested in me by prior annual HHS appropriations acts, prior to the effective date of the delegation.

Dated: November 2, 2021.

Xavier Becerra,

Secretary.

[FR Doc. 2021–24248 Filed 11–4–21; 8:45 am]

BILLING CODE 4151–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to internal NCI committees that will decide whether NCI should support requests and make available contract resources for development of the potential therapeutic to improve the treatment of various forms of cancer. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; OCT2021 Cycle 39 NExT SEP Committee Meeting.

Date: December 14, 2021,

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To evaluate the NCI Experimental Therapeutics Program Portfolio.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Room 3A44, Bethesda, Maryland 20892 (WebEx Meeting).

Contact Persons: Barbara Mroczkowski, Ph.D., Executive Secretary, Discovery Experimental Therapeutics Program, National Cancer Institute, NIH, 31 Center Drive, Room 3A44, Bethesda, Maryland 20817, 301–496–4291, *mroczkoskib@mail.nih.gov.*

Toby Hecht, Ph.D., Executive Secretary, Development Experimental Therapeutics Program, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 3W110, Rockville, Maryland 20850, 240–276–5683, *toby.hecht2@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 2, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24237 Filed 11–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel Support for Research Excellence (SuRE) Award (R16).

Date: November 30–December 1, 2021.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Cynthia Louise De La Fuente, Ph.D., Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Rockville, MD 20852, 240–669–2740, *delafuentecl@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 1, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24188 Filed 11–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Consortium for Innovative HIV/AIDS Vaccine and Cure Research (UM1 Clinical Trial Not Allowed).

Date: December 1, 2021.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases National Institutes of Health 5601 Fishers Lane, Room 3G11A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: J. Bruce Sundstrom, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G11A, Bethesda, MD 20892–9823, 240–669–5045, *sundstromj@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 1, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24186 Filed 11–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings (Parent R13 Clinical Trial Not Allowed).

Date: December 1, 2021.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Trinh T. Tran, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–5843, *trinh.tran@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 1, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24189 Filed 11–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Interactive Digital Media STEM Resources for Pre-College and Informal Science Education Audiences (SBIR/STTR).

Date: November 30, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Marie-Jose Belanger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm 6188, MSC 7804, Bethesda, MD 20892, (301) 435–1267, *belangerm@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR19–294: Early-Stage Preclinical Validation of Therapeutic Leads for Diseases of Interest to the NIDDK.

Date: December 1, 2021.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Raul Rojas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6185, Bethesda, MD 20892, (301)451–6319, *rojasr@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–TW–21–004: Launching Future Leaders in Global Health (LAUNCH) Research Training Program.

Date: December 3, 2021.

Time: 10:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maureen Shuh, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–480–4097, *maureen.shuh@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Anti-infective Therapeutics.

Date: December 8, 2021.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barna Dey, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, Bethesda, MD 20892, 301–451–2796, *bdey@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; GEO Health: Interdisciplinary Hubs for Research and Training.

Date: December 8–9, 2021.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, *sarita.sastry@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 1, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24187 Filed 11–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

Date: November 30–December 1, 2021.

Time: 10:00 a.m. to 3:15 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alicia J. Dombroski, Ph.D., Director, Division of Extramural Activities, Natl. Inst. of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD 20892.

Information is also available on the Institute's/Center's home page: *https://www.nidcr.nih.gov/about-us/advisory-committees/board-scientific-counselors,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: November 2, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24238 Filed 11–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; NRSA Institutional Research Training (T32).

Date: December 1, 2021.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–9734, *millerda@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; NIMH Biobehavioral Research Awards for Innovative New Scientists (NIMH BRAINS).

Date: December 1, 2021.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Erin E. Gray, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Boulevard, NSC 6152B, Bethesda, MD 20892, 301–402–8152, *erin.gray@nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; HIV/AIDS Review (P30, R25).

Date: December 2, 2021.

Time: 11:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892–9608, 301–443–4525, *steinerr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 2, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–24239 Filed 11–4–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these

documents, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Project: Treatment Episode Data Set (TEDS) (OMB No. 0930–0335)—Extension

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting an extension to collect the Treatment Episode Data Set (TEDS) data collection (OMB No. 0930–0335), which expires on April 30, 2022. TEDS is a compilation of client-level substance use treatment admission and discharge data submitted by states on clients treated in facilities that receive state funds. SAMHSA is also requesting an extension to collect the client-level mental health admission and update/discharge data (MH–TEDS/MH–CLD) submitted by states on clients treated in facilities that receive state funds (also OMB No. 0930–0335).

TEDS/MH–TEDS/MH–CLD data are collected to obtain information on the number of admissions and updates/discharges at publicly funded substance use treatment and mental health services facilities and on the characteristics of clients receiving services at those facilities.

TEDS/MH–TEDS/MH–CLD also monitor trends in the demographic, substance use, and mental health characteristics of admissions. In addition, several of the data elements used to calculate performance measures for the Substance Abuse Block Grant (SABG) and Mental Health Block Grant (MHBG) applications are collected through the TEDS/MH–TEDS/MH–CLD.

Most states collect the TEDS/MH–TEDS/MH–CLD data elements from their treatment providers for their own administrative purposes and are able to submit a cross-walked extract of their data to TEDS/MH–TEDS/MH–CLD. No changes are expected in the TEDS/MH–TEDS/MH–CLD data elements that are collected.

Estimated annual burden for the separate TEDS/MH–TEDS/MH–CLD activities is as follows:

Type of activity	Number of respondents (states/jurisdictions)	Responses per respondent	Total responses	Hours per response	Total burden hours
TEDS Admission Data	52	4	208	6.25	1,300
TEDS Discharge Data	52	4	208	8.25	1,716
TEDS Crosswalks	5	1	5	10	50
MH–CLD BCI Data	30	1	30	30	900
MH–CLD SHR Data	30	1	30	5	150
MH–TEDS Admissions Data	29	4	116	6.25	725
MH–TEDS Update/Discharge Data	29	4	116	8.25	957
MH–TEDS Crosswalks	10	1	10	10	100
Total	59	.....	723	.....	5,898

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Carlos Graham,

Reports Clearance Officer.

[FR Doc. 2021–24221 Filed 11–4–21; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2021–0013; OMB No. 1660–0002]

Agency Information Collection Activities: Proposed Collection; Comment Request; Disaster Assistance Registration

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 60-Day notice of renewal and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on an extension, without change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning Disaster Assistance Registration, COVID–19 Funeral Assistance Registration, and Disaster Assistance Individuals and Households Program (IHP) Occupancy & Ownership Documentation.

DATES: Comments must be submitted on or before January 4, 2022.

ADDRESSES: Please submit comments at *www.regulations.gov* under Docket ID FEMA–2021–0013. Follow the instructions for submitting comments.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Brian Thompson, Supervisory Program Specialist, FEMA, Recovery Directorate at 540–686–3602 or *Brian.Thompson6@fema.dhs.gov.* You may contact the Information Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The Robert T. Stafford Disaster Relief and Emergency Assistance Act (Pub. L. 93–288) (the Stafford Act), as amended, is the legal basis for FEMA to provide financial assistance and services to individuals who apply for disaster assistance benefits in the event of a federally-declared disaster. Regulations in Title 44 of the Code of Federal Regulations, Subpart D, ''Federal Assistance to Individuals and Households,'' implement the policy and procedures set forth in section 408 of the Stafford Act. This program provides financial assistance and, if necessary, direct assistance to eligible individuals

and households who, as a direct result of a major disaster, have necessary expenses and serious needs that are unable to be met through other means. Individuals and households may apply for assistance (Registration Intake) under the Individuals and Households Program (IHP) in person, via telephone, or internet. FEMA provides financial assistance under the Other Needs Assistance provision of the IHP to individuals or households affected by a major disaster to meet disaster-related funeral expenses under Section 408(e)(1) of the *Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), Public Law 93–288, as amended.*

Historically, the agency has utilized a combination of public and commercial validation of ownership and or occupancy, which impacts eligibility for Housing Assistance and some forms of Other Needs Assistance. This update applies to the proposed expansion of the acceptable documentation applicants can submit to FEMA to verify the occupancy and/or ownership of their primary residence and establish eligibility for disaster assistance.

Collection of Information

Title: Disaster Assistance Registration.

Type of Information Collection: Extension, without change, of a currently approved information collection number.

OMB Number: 1660–0002.

FEMA Forms: FEMA Form FF–104–FY–21–123 (formerly 009–0–1T (English)), Tele-Registration, Disaster Assistance Registration; FEMA Form FF–104–FY–21–123–A (formerly 009–0–1T (Spanish)), Tele-Registration, Registro Para Asistencia De Desatre; FEMA Form FF–104–FY–21–123–COVID–FA (formerly 009–0–1T–COVID–FA (English)), Tele-Registration, COVID–19 Funeral Assistance; FEMA Form FF–104–FY–21–125 (formerly 009–0–1Int (English)), internet, Disaster Assistance Registration; FEMA Form FF–104–FY–21–125–A (formerly 009–0–2Int (Spanish)), internet, Registro Para Asistencia De Desastre; FEMA Form FF–104–FY–21–122 (formerly 009–0–1 (English)), Paper Application/Disaster Assistance Registration; FEMA Form FF–104–FY–21–122–A (formerly 009–0–2 (Spanish)), Solicitud en Papel/Registro Para Asistencia De Desastre; FEMA Form FF–104–FY–21–128 (formerly 009–0–3 (English)), Declaration and Release; FEMA Form FF–104–FY–21–128–A (formerly 009–0–4 (Spanish)), Declaración Y Autorización; FEMA Form FF–104–FY–21–127 (formerly 009–0–5 (English)), Manufactured Housing Unit Revocable License and Receipt for Government Property; FEMA Form FF–104–FY–21–127–A (formerly 009–0–6 (Spanish)), Las Casas Manufacturadas Unidad Licencia Revocable y Recibo de la Propiedad del Gobierno; Requests for Information (RFI)

Abstract: The forms in this collection are used to obtain pertinent information to provide financial assistance, and if necessary, direct assistance to eligible individuals and households who, as a direct result of a disaster or emergency, have uninsured or under-insured, necessary or serious expenses they are unable to meet. This extension, without change, will also support the continued ability to provide COVID–19 Funeral Assistance to individuals who are responsible for a deceased individual's funeral expenses and the expansion of the acceptable documentation applicants can submit to FEMA to verify the occupancy and/or ownership of their primary residence and establish eligibility for disaster assistance.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 2,043,134.

Estimated Number of Responses: 2,043,134.

Estimated Total Annual Burden Hours: 642,031.

Estimated Total Annual Respondent Cost: $25,199,717.

Estimated Respondents' Operation and Maintenance Costs: $0.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $20,525,700.

Comments

Comments may be submitted as indicated in the **ADDRESS** 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.

Millicent L. Brown,

Acting Branch Chief, Records Management Branch, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2021–24286 Filed 11–4–21; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Cybersecurity and Infrastructure Security Agency

Notice of the Establishment of the Cybersecurity and Infrastructure Security Agency Cybersecurity Advisory Committee

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: Notice of new Federal Advisory Committee.

SUMMARY: Per Federal Advisory Committee Act (FACA) regulations and guidelines, DHS is announcing the establishment of the CISA Cybersecurity Advisory Committee, a new Federal Advisory Committee, for public awareness.

FOR FURTHER INFORMATION CONTACT: Megan Tsuyi, 202–594–7374, *CISA_CybersecurityAdvisoryCommittee@cisa.dhs.gov.*

SUPPLEMENTARY INFORMATION: The CISA Cybersecurity Advisory Committee was officially established on June 25, 2021. The Committee is established under the *National Defense Authorization Act* for Fiscal Year 2021, Public Law 116–283 (NDAA). Pursuant to section 871(a) of the *Homeland Security Act of 2002,* 6 United States Code (U.S.C.) 451(a), this statutory committee is established in accordance with and operates under the provisions of the *Federal Advisory Committee Act* (FACA) (5 U.S.C., Appendix). The primary purpose of the CISA Cybersecurity Advisory Committee will be to develop, at the request of the CISA Director, recommendations on matters related to the development, refinement, and implementation of policies, programs, planning, and training pertaining to the cybersecurity mission of the Agency. The CISA Cybersecurity Advisory Committee will operate in an advisory capacity only and is in the public interest.

This notice is provided in accordance with the *Federal Advisory Committee*

Act, as amended. The CISA Cybersecurity Advisory Committee will terminate two years from the date of its establishment, unless extended by the Secretary. For additional information on the committee, please visit *https://cisa.gov/cisa-cybersecurity-advisory-committee.*

Alejandro N. Mayorkas,

Secretary, Department of Homeland Security.

[FR Doc. 2021–24254 Filed 11–4–21; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2021–0015]

Public Perceptions of Emerging Technology

AGENCY: Science and Technology Directorate (S&T), Department of Homeland Security (DHS).

ACTION: 30-Day Notice of Information Collection; New request for comment, 1640–NEW.

SUMMARY: DHS S&T will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The survey will collect information from the public regarding applications of artificial intelligence (AI), including facial recognition. DHS has already used or piloted AI-based technologies in several of its key functions, including customs and border protection, transportation security, and investigations. However, AI in general and facial recognition in particular are not without public controversy, including concerns about bias, security, and privacy. Therefore, understanding how the public perceives these technologies, and then designing and deploying them in a manner responsive to the public's concerns, is critical in gaining public support for DHS's use of these technologies.

DATES: Comments are encouraged and accepted until December 6, 2021.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments, identified by docket number DHS–2021–0015, should be submitted via the Federal eRulemaking Portal: *https://www.regulations.gov.* The comments submitted via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). Please follow the instructions on the site for submitting comments.

FOR FURTHER INFORMATION CONTACT: Program Manager: Kathleen Deloughery, *kathleen.deloughery@hq.dhs.gov* or (202) 254–6189 (Not a toll free number).

SUPPLEMENTARY INFORMATION: DHS, in accordance with the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. DHS is soliciting comments on the proposed information collection request (ICR) that is described below. DHS 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.

Agency: Department of Homeland Security (DHS).

Title: Public Perceptions Of Emerging Technologies.

OMB Number: Insert.

Frequency: One Per Request.

Affected Public: Individuals And Households.

Number of Respondents: 3000.

Estimated Time per Respondent: 12 Minutes.

Total Burden Hours: 600.

Dated: March 22, 2021.

Gregg Piermarini,

DHS S&T Chief Information Officer.

Editorial note: This document was received for publication by the Office of the Federal Register on November 2, 2021.

[FR Doc. 2021–24247 Filed 11–4–21; 8:45 am]

BILLING CODE 9112–FL–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6299–D–01]

Delegation of Authority for the Office of the Chief Financial Officer

AGENCY: Office of the Secretary, HUD.

ACTION: Notice of delegation of authority.

SUMMARY: In this notice, the Secretary of HUD, pursuant to the Chief Financial Officers Act of 1990 (CFO Act), which established the position of the Chief Financial Officer within HUD, is delegating authority to the Chief Financial Officer and the Deputy Chief Financial Officer for certain responsibilities with respect to the financial management activities, systems, and operations of the Department.

DATES: *Applicable Date:* October 29, 2021.

FOR FURTHER INFORMATION CONTACT: John B. Shumway, Assistant General Counsel, Administrative Law Division, Department of Housing and Urban Development, at 451 7th Street SW, Room 9262; Washington, DC 20410–0500 or telephone number 1–202–402–5190 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the Federal Relay Service at 1–800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION: The Secretary is delegating to the Chief Financial Officer and the Deputy Chief Financial Officer those responsibilities enumerated in the CFO Act (31 U.S.C. 901 *et seq.*), and HUD's Fiscal Year (FY) 2003 Appropriations Act (Pub. L. 108–7, approved February 20, 2003), relating to the financial management activities related to the programs and operation of HUD.

Accordingly, the Secretary delegates as follows:

Section A. Authority Delegated

The Secretary hereby delegates the following responsibilities, functions, and duties to the Chief Financial Officer and the Deputy Chief Financial Officer:

1. To serve as the principal advisor to the Secretary on financial management;

2. To supervise, coordinate, and establish policies to govern all financial management activities and operations of the Department consistent with the requirements of law and regulation; to oversee the development, administration, and coordination of the financial and accounting functions of the Department; and to issue such policies and directives as may be necessary to carry out the duties of the Chief Financial Officer;

3. To develop and maintain a financial management system for the Department (including accounting and related transaction systems; internal control systems; financial reporting systems; and credit, cash and debt management systems). To coordinate systems for audit compliance with external organizations that have responsibilities for the use and

management of funds and other resources for which the Department has responsibility;

4. To provide direction to ensure the Department's compliance with Office of Management and Budget (OMB), Government Accountability Office (GAO), Department of the Treasury (Treasury), and legislative accounting and financial management requirements; and to strengthen internal accounting and administrative controls to prevent waste, fraud, and abuse in Federal programs;

5. To assist in the financial execution of the Department's budget in relation to actual expenditures and to prepare timely performance reports for senior managers;

6. To develop, maintain, and revise an annual plan to bring the financial management systems of the Department into full compliance with established policies and standards and to oversee execution of the plan; and to estimate resource requirements for the Office of the Chief Financial Officer for inclusion in the Department's budget requests;

7. To coordinate with the Inspector General to ensure that all Department financial activities are regularly audited, and to ensure that adopted recommendations related to Department financial management issues are promptly implemented;

8. To be responsible for the financial management needs of the Department, to report to the Congress and to external agencies such as OMB, the Treasury and the GAO on financial management performance, Department financial statements, and other information requests required by law and regulation, and to develop and maintain a departmental financial management information system;

9. To provide policy direction and guidance to the designated Comptrollers of principal Department organizational components, including the Federal Housing Administration (FHA), and Government National Mortgage Association (GNMA), as well as other departmental staff, with respect to financial management policies, standards, and responsibilities;

10. To process and sign Apportionments/Reapportionments Schedules and Advice of Allotments in accordance with applicable OMB Circulars;

11. Where not inconsistent with regulations pertaining to proceedings before administrative judges, to establish and maintain policies and procedures for claims collection and coordinate claims collection activities in the field offices and at Headquarters;

12. To appoint Disbursement and Certifying Officers to approve the disbursal of agency funds;

13. To serve as advisor to the Secretary and to other departmental officials in matters relating to budget formulation and execution, and to advise and assist program offices in their budgetary responsibilities and appraise the effectiveness of these activities; advise on budget and fiscal implications of policy and legislative proposals; and administer the issuance of staff ceilings and monitor staff usage in the Department;

14. To continue to ensure that HUD offices have an adequate system of funds control, including working with such offices to strengthen such controls to prevent or mitigate any potential Anti-deficiency Act (31 U.S.C. 1341 *et seq.*) violations; and

15. To implement and administer the Emergency Homeowners' Loan Program within the Emergency Homeowners' Relief Act, as amended (12 U.S.C. 2701 *et seq.*), in cooperation with HUD's Office of Policy Development and Research and HUD's Office of Housing.

The Secretary may revoke any discretionary authority authorized herein, in whole or part, at any time.

Section B. Authority Excepted

The authority delegated in this Notice does not include the authority to sue and be sued. The authority delegated to the Deputy Chief Financial Officer herein does not include the authority to issue and waive regulations.

Section C. Authority To Redelegate

The Chief Financial Officer and the Deputy Chief Financial Officer are authorized to retain or redelegate authorities delegated under Section A above to the Assistant Chief Financial Officers in the Office of the Chief Financial Officer, with the exception of the authority to issue and waive regulations.

Section D. Authority Superseded

This delegation supersedes all prior delegations of authority from the Secretary to the Chief Financial Officer and to the Deputy Chief Financial Officer.

Authority: Section 7(d) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: October 29, 2021.

Marcia L. Fudge,

Secretary.

[FR Doc. 2021–24250 Filed 11–4–21; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2021–N185; FX3ES11130300000–212–FF03E00000]

Endangered and Threatened Wildlife and Plants; Initiation of 5-Year Status Reviews of Six Listed Animal and Plant Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of reviews; request for information.

SUMMARY: We, the U.S. Fish and Wildlife Service, are initiating 5-year status reviews under the Endangered Species Act of 1973, as amended, for three plant and three animal species. A 5-year status review is based on the best scientific and commercial data available at the time of the review; therefore, we are requesting submission of any such information that has become available since the last review for the species.

DATES: To ensure consideration, please send your written information by January 4, 2022. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: For instructions on how to submit information for each species, see the table in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: To request information, contact the appropriate person in the table in the **SUPPLEMENTARY INFORMATION** section or, for general information, contact Laura Ragan, via email at *laura_ragan@fws.gov* or by phone at 612–713–5157. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We are initiating 5-year status reviews under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), for three plant and three animal species. A 5-year status review is based on the best scientific and commercial data available at the time of the review; therefore, we are requesting submission of any such information that has become available since the last review for the species.

Why do we Conduct 5-year reviews?

Under the ESA, we maintain Lists of Endangered and Threatened Wildlife and Plants (which we collectively refer to as the List) in the Code of Federal Regulations (CFR) at 50 CFR 17.11 (for animals) and 17.12 (for plants). Section 4(c)(2)(A) of the ESA requires us to

review each listed species' status at least once every 5 years. Our regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing those species under active review. For additional information about 5-year reviews, go to http://www.fws.gov/endangered/what-we-do/recovery-overview.html, scroll down to ''Learn More about 5-Year Reviews,'' and click on our factsheet.

What information do we consider in our review?

A 5-year review considers the best scientific and commercial data that have become available since the current listing determination or most recent status review of each species, such as:

(A) Species biology, including but not limited to population trends, distribution, abundance, demographics, and genetics;

(B) Habitat conditions, including but not limited to amount, distribution, and suitability;

(C) Conservation measures that have been implemented that benefit the species;

(D) Threat status and trends in relation to the five listing factors (as defined in section 4(a)(1) of the ESA); and

(E) Other new information, data, or corrections, including but not limited to taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

New information will be considered in the 5-year review and ongoing recovery programs for the species.

What species are under review?

This notice announces our active 5-year status reviews of the species in the following table.

Common name	Scientific name	Taxonomic group	Listing status	Where listed	Final listing rule (**Federal Register** citation and publication date)	Contact person, email, phone	Contact person's U.S. mail address
Winged mapleleaf ..	*Quadrula fragosa*	Clam	E	AL, AR, MN, MO, OK, TN, WI.	56 FR 28345; June 20, 1991.	Nick Utrup, *nick_utrup@fws.gov*, 952–252–0092, ext. 204.	USFWS, 4101 American Boulevard East, Bloomington, MN 55425.
Dwarf lake iris	*Iris lacustris*	Plant	T	MI, WI	53 FR 37972; September 28, 1988.	Carrie Tansy, *carrie_tansy@fws.gov*, 517–351–8375.	USFWS, 2651 Coolidge Road, Suite 101, East Lansing, MI 48823.
Fassett's locoweed	*Oxytropis campestris* var. *chartacea*.	Plant	T	WI	53 FR 37970; September 28, 1988.	Jill Utrup, *jill_utrup@fws.gov*, 952–252–0092, ext. 207.	USFWS, 4101 American Boulevard East, Bloomington, MN 55425.
Tumbling creek cave snail.	*Antrobia culveri* ...	Snail	E	MO	67 FR 52879; August 14, 2002.	Iwona Kuczynska, *Iwona_Kuczynska@fws.gov*, 573–234–5011.	USFWS, 101 Park DeVille Drive, Suite A, Columbia, MO 65203.
Mead's milkweed ...	*Asclepias meadii*	Plant	T	IA, IL, IN, KS, MO, WI.	53 FR 33992; September 1, 1988.	Ashley Riedel, *ashley_riedel@fws.gov*, 573–234–2132, ext. 404.	USFWS, 101 Park DeVille Drive, Suite A, Columbia, MO 65203.
Rusty patched bumble bee.	*Bombus affinis*	Insect	E	CT, DC, DE, GA, IA, IL, IN, KY, MA, MD, ME, MI, MN, MO, NC, ND, NH, NJ, NY, OH, PA, RI, SC, SD, WI, TN, VT, WV.	82 FR 3186; January 11, 2017.	Tamara Smith, *tamara_smith@fws.gov*, 952–252–0092, ext. 219.	USFWS, 4101 American Boulevard East, Bloomington, MN 55425.

Request for Information

To ensure that a 5-year review is complete and based on the best available scientific and commercial information, we request new information from all sources. See ''What Information Do We Consider in Our Review?'' for specific criteria. If you submit information, please support it with documentation such as maps, bibliographic references, methods used to gather and analyze the data, and/or copies of any pertinent publications, reports, or letters by knowledgeable sources.

How do I ask questions or provide information?

If you wish to provide information for any species listed above, please submit your comments and materials to the appropriate contact in the table above. You may also direct questions to those contacts. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800–877–8339 for TTY assistance.

Public Availability of Submissions

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We publish this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Lori Nordstrom,

Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2021–24208 Filed 11–4–21; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R4–ES–2021–0122; FXES11130400000EA–123–FF04EF4000]

Receipt of Incidental Take Permit Application and Proposed Habitat Conservation Plan for the Sand Skink, Lake County, FL; Categorical Exclusion

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment and information.

SUMMARY: We, the Fish and Wildlife Service (Service), announce receipt of an application from VK Avalon Groves LLC (applicant) for an incidental take permit (ITP) under the Endangered Species Act. The applicant requests the ITP to take the federally listed sand skink incidental to construction in Lake County, Florida. We request public comment on the application, which includes the applicant's proposed

habitat conservation plan (HCP), and the Service's preliminary determination that this HCP qualifies as ''low-effect,'' categorically excluded, under the National Environmental Policy Act. To make this determination, we used our environmental action statement and low-effect screening form, both of which are also available for public review.

DATES: We must receive your written comments on or before December 6, 2021.

ADDRESSES:

Obtaining Documents: You may obtain copies of the documents online in Docket No. FWS–R4–ES–2021–0122 at *http://www.regulations.gov.*

Submitting Comments: If you wish to submit comments on any of the documents, you may do so in writing by any of the following methods:

- *Online: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R4–ES–2021–0122.
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–R4–ES–2021–0122; U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Erin M. Gawera, by telephone at (904) 731–3121 or via email at *erin_gawera@fws.gov.* Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the Fish and Wildlife Service (Service), announce receipt of an application from VK Avalon Groves LLC (Serenoa Commercial) for an incidental take permit (ITP) under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The applicant requests the ITP to take the federally listed sand skink (*Neoseps reynoldsi*) incidental to the construction of a commercial development (project) in Lake County, Florida. We request public comment on the application, which includes the applicant's proposed habitat conservation plan (HCP), and on the Service's preliminary determination that this HCP qualifies as ''low-effect,'' categorically excluded, under the National Environmental Policy Act (NEPA; 42 U.S.C. 4231 *et seq.*). To make this determination, we used our environmental action statement and low-effect screening form, both of which are also available for public review.

Project

The applicant requests a 5-year ITP to take sand skinks through the conversion of approximately 1.2 acres (ac) of occupied sand skink foraging and sheltering habitat incidental to the construction of a commercial development located on a 24-ac parcel in Section 13; Township 24 South; Range 26 East, Lake County, Florida, identified by Parcel ID numbers 3–24–26–0200–X01–00000 and 13–24–26–0200–C8B–00000. The applicant proposes to mitigate for take of the skink by purchasing credits equivalent to 2.4 acres of occupied habitat from Lake Wales Ridge Conservation Bank or another Service-approved conservation bank prior to any clearing activities.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, be aware that your entire comment, including your personal identifying information, may be made available to the public. While you may request that we withhold your personal identifying information, we cannot guarantee that we will be able to do so.

Our Preliminary Determination

The Service has made a preliminary determination that the applicant's project, including land clearing, infrastructure building, landscaping, and the proposed mitigation measures, would individually and cumulatively have a minor or negligible effect on sand skinks and the environment. Therefore, we have preliminarily concluded that the ITP for this project would qualify for categorical exclusion and the HCP is low effect under our NEPA regulations at 43 CFR 46.205 and 46.210. A low-effect HCP is one that would result in (1) minor or negligible effects on federally listed, proposed, and candidate species and their habitats; (2) minor or negligible effects on other environmental values or resources; and (3) impacts that, when considered together with the impacts of other past, present, and reasonably foreseeable similarly situated projects, would not over time result in significant cumulative effects to environmental values or resources.

Next Steps

The Service will evaluate the application and the comments received to determine whether to issue the requested permit. We will also conduct an intra-Service consultation pursuant to section 7 of the ESA to evaluate the effects of the proposed take. After considering the above findings, we will determine whether the permit issuance criteria of section 10(a)(1)(B) of the ESA have been met. If met, the Service will issue ITP number PER0015886–0 to VK Avalon Groves LLC.

Authority

The Service provides this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.32) and NEPA (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6 and 43 CFR 46.305).

Robert L. Carey,

Division Manager, Environmental Review, Florida Ecological Services Field Office.

[FR Doc. 2021–24124 Filed 11–4–21; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R7–ES–2021–0055; FXES111607MRG01–212–FF07CAMM00]

Marine Mammals; Incidental Take During Specified Activities; Proposed Incidental Harassment Authorization for Southern Beaufort Sea Stock of Polar Bears in the Prudhoe Bay Unit and Point Thomson Unit of the North Slope of Alaska

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application; proposed incidental harassment authorization; notice of availability of draft environmental assessment; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, received a request under the Marine Mammal Protection Act of 1972 from JADE Energy, LLC, for authorization to take by Level B harassment a small number of polar bears from the Southern Beaufort Sea (SBS) stock incidental to oil and gas exploratory activities scheduled to occur between December 1, 2021, through November 30, 2022. These activities include mobilization, constructing ice roads and ice pads, drilling wells, and associated cleanup in the Prudhoe Bay Unit and Point Thomson Unit of the North Slope of Alaska. Mobilization would occur in December 2021, along a winter trail stretching east from Deadhorse, Alaska, to Point Thomson, Alaska. Prepacking of snow and construction of ice roads and pads would begin mid-December 2021, and drilling would begin at JADE #1 pad in late-January 2022. If conditions are favorable, drilling on JADE #2 pad would take place in mid-March 2022, preceding cleanup activities, which are proposed to be completed by July 15, 2022. We estimate these activities may result in the nonlethal incidental take of up to two

SBS stock polar bears. This proposed authorization, if finalized, will be for take of two SBS stock polar bears by Level B harassment only. No lethal or Level A take of polar bears is likely or requested, and, therefore, such take is not included in this proposed authorization.

DATES: Comments on this proposed incidental harassment authorization and the accompanying draft environmental assessment must be received by December 6, 2021.

ADDRESSES: *Document availability:* You may view this proposed authorization, the application package, supporting information, draft environmental assessment, and the list of references cited herein at *https://www.regulations.gov* under Docket No. FWS–R7–ES–2021–0055, or these documents may be requested as described under **FOR FURTHER INFORMATION CONTACT**. You may submit comments on the proposed authorization by one of the following methods:

- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–R7–ES–2012–0055, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803.
- *Electronic submission:* Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments to Docket No. FWS–R7–ES–2021–0055.

We will post all comments at *https://www.regulations.gov.* You may request that we withhold personal identifying information from public review; however, we cannot guarantee that we will be able to do so. See Request for Public Comments for more information.

FOR FURTHER INFORMATION CONTACT: Charles Hamilton, U.S. Fish and Wildlife Service, MS 341, 1011 East Tudor Road, Anchorage, Alaska 99503, by email at *R7mmmregulatory@fws.gov* or by telephone at 1–800–362–5148. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, 7 days a week.

SUPPLEMENTARY INFORMATION:

Background

Section 101(a)(5)(D) of the Marine Mammal Protection Act of 1972 (MMPA; 16 U.S.C. 1361, *et seq.*) authorizes the Secretary of the Interior (Secretary) to allow, upon request, the incidental, but not intentional, taking by harassment of small numbers of marine mammals in response to requests by U.S. citizens (as defined in title 50 of the Code of Federal Regulations (CFR) in part 18, at 50 CFR 18.27(c)) engaged in a specified activity (other than commercial fishing) within a specific geographic region for periods of not more than 1 year. The Secretary has delegated authority for implementation of the MMPA to the U.S. Fish and Wildlife Service (Service or we). According to the MMPA, the Service shall authorize this harassment if we find that the total of such taking for the 1-year period:

(1) Is of small numbers of marine mammals of a species or stock;

(2) will have a negligible impact on such species or stocks; and

(3) will not have an unmitigable adverse impact on the availability of these species or stocks for taking for subsistence uses by Alaska Natives.

If the requisite findings are made, we issue an authorization that sets forth the following, where applicable:

(a) Permissible methods of taking;

(b) means of effecting the least practicable adverse impact on such species or stock and its habitat and the availability of the species or stock for subsistence uses; and

(c) requirements for monitoring and reporting of such taking by harassment, including, in certain circumstances, requirements for the independent peer review of proposed monitoring plans or other research proposals.

The term ''take'' means to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal. ''Harassment'' means any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (the MMPA defines this as ''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 (the MMPA defines this as ''Level B harassment'').

The terms ''negligible impact'' and ''unmitigable adverse impact'' are defined in 50 CFR 18.27 (*i.e.,* regulations governing small takes of marine mammals incidental to specified activities) as follows: ''Negligible impact'' is 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. ''Unmitigable adverse impact'' means an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by (i) causing the marine mammals to abandon or avoid hunting areas, (ii) directly displacing subsistence users, or (iii) placing physical barriers between the marine mammals and the subsistence hunters; and (2) that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

The term ''small numbers'' is also defined in 50 CFR 18.27. However, we do not rely on that definition here as it conflates ''small numbers'' with ''negligible impacts.'' We recognize ''small numbers'' and ''negligible impact'' as separate and distinct considerations when reviewing requests for incidental harassment authorizations (IHA) under the MMPA (see *Natural Res. Def. Council, Inc.* v. *Evans,* 232 F. Supp. 2d 1003, 1025 (N.D. Cal. 2003)). Instead, for our small numbers determination, we estimate the likely number of takes of marine mammals and evaluate if that take is small relative to the size of the species or stock.

The term ''least practicable adverse impact'' is not defined in the MMPA or its enacting regulations. For this IHA, we ensure the least practicable adverse impact by requiring mitigation measures that are effective in reducing the impact of project activities, but they are not so restrictive as to make project activities unduly burdensome or impossible to undertake and complete.

If the requisite findings are made, we will issue an IHA, which will set forth the following, where applicable: (i) Permissible methods of taking; (ii) 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 subsistence uses by coastal-dwelling Alaska Natives (if applicable); and (iii) requirements for monitoring and reporting such taking by harassment.

Summary of Request

On May 19, 2021, the Service received a request on behalf of JADE Energy, LLC (JADE), for nonlethal incidental harassment of small numbers of SBS stock polar bears during mobilization, well drilling, construction of ice roads and pads, and cleanup activities in the Prudhoe Bay Unit (PBU) and Point Thomson Unit (PTU) of the North Slope of Alaska for a period of 1 year (December 1, 2021, to November 30, 2022) (hereafter referred to as the ''Request''). After discussions with the Service regarding project timelines and mitigation measures, we received

project shapefiles on May 25, 2021, and a revised Request on June 9, 2021, which was deemed adequate and complete. JADE further amended their June 9, 2021, Request to include changes to the location of JADE #2 pad, JADE #2 ice road, and planned location of the winter trail. This final Request—which is also adequate and complete—was received August 2, 2021.

Description of Specified Activities and Specific Geographic Region

The specified activities (hereafter referred to as the ''project'') consists of mobilization activities, construction of ice roads and pads, drilling wells, and cleanup and supporting activities. All activities occur within Alaska's North Slope planning area. The North Slope planning area has 1,225 tracts that lie between the National Petroleum Reserve—Alaska (NPRA) and the boundary of the Arctic National Wildlife Refuge (Arctic Refuge). The southern boundary of the North Slope planning area is the Umiat baseline. Mobilization activities will stretch east from Deadhorse in the PBU to Point Thomson in the PTU and will not extend into the Arctic Refuge. JADE is the majority owner and operator of Alaska State oil and gas lease ADL 343112, which is located approximately 96.6 kilometers (km) (60 miles [mi]) east of Prudhoe Bay, Alaska, and 94 km (59 mi) west of Kaktovik, Alaska. ADL 343112 is located within the southeast portion of the PTU and consists of 266.06 hectares (ha) (657.45 acres [ac]) of land. Facilities used during the duration of the project activities are located in Point Thomson at PTU central pad. JADE #1 is approximately 9.09 km (5.65 mi) southeast, and JADE #2 is located approximately 6.37 km (3.96 mi) southwest, of PTU central pad (figure 1).

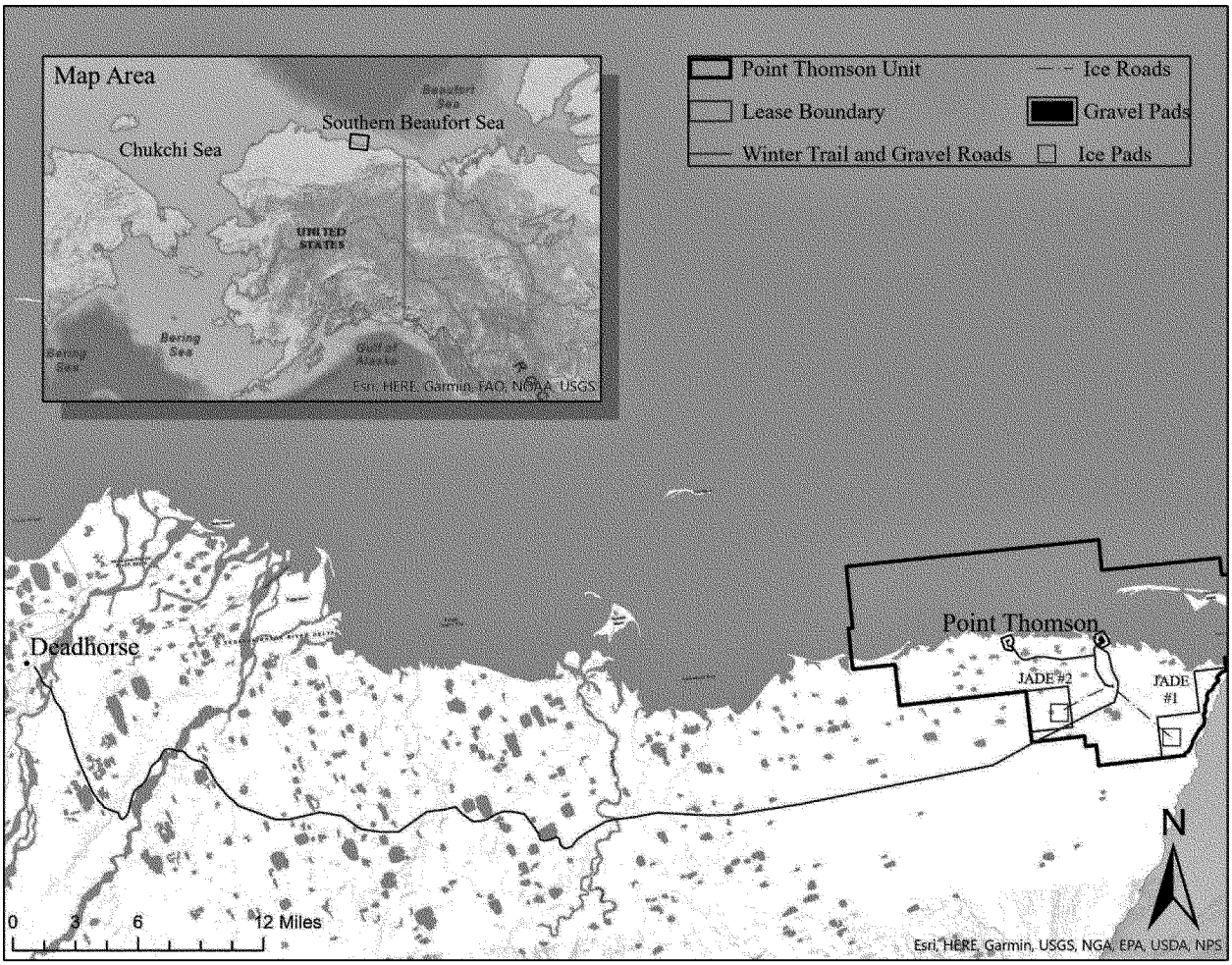

Figure 1—Specific geographic region and proposed ice roads and pads.

Staging and Mobilization

An overland winter trail stretching from Deadhorse to Point Thomson will be used for initial mobilization and resupply throughout the project. The winter trail is planned to be constructed by Exxon Mobil Alaska Production Inc. (EMAP); however, if EMAP is unable to construct the winter trail prior to JADE activities, JADE will construct the winter trail. Approximately 42 round trips of drilling supplies, fuel, and materials will be hauled by Pisten Bullys and Steiger tractor trailer units along the winter trail. During drilling and testing, supply hauls along the winter trail will be limited to every third day, generally consisting of two Pisten Bullys and two Steigers. Mobilization would begin January 16, 2022, and demobilization would be completed by April 29, 2022, with equipment being staged at PTU West Pad during the summer.

Ice Road and Pad Construction

One ice road, 5.95 km (3.7 mi) long, will be constructed south from the end of the PTU gravel road system to JADE #1—a 3.34-ha (8.26-ac) ice pad. A secondary ice road, 4.1 km (2.55 mi) long, will be constructed west from the PTU gravel road system to JADE #2, which will be similar in size to JADE #1. Preparation for the construction of ice roads and pads is set to occur from December 15, 2021, to January 2, 2022, and would involve two operators and approximately 7 days of work. Construction would proceed immediately after this activity, with eight operators working 12-hour day shifts for approximately 8 days to be completed by January 16, 2022. Maintenance of roads and pads would be required throughout the project and would be conducted by five operators working a day shift. Once drilling begins, ice roads will have daily traffic to shuttle crew to and from the pad(s) via busses from Point Thomson with approximately four trips per day.

Well Drilling and Cleanup

Drilling equipment will be mobilized from PTU West Pad to JADE #1 starting on January 16, 2022, and drilling will begin January 29, 2022. If drilling attempts are successful at JADE #1, the drill rig and associated drilling equipment will be moved to JADE #2 on March 7, 2022. If drilling is conducted at JADE #2, activities will begin approximately on March 13, 2022, and be completed on April 20, 2022.

Following drilling activities, JADE has proposed to contract one helicopter in early July to perform flyovers of the project area to identify any debris that may have been left behind during winter operations. The cleanup crew will inspect all camp locations and any area where field activities occurred. All cleanup work is to be completed by July 15, 2022. The area of cleanup will not extend beyond the project area, and during transit aircraft used are expected to maintain 1,500 feet (ft) altitude above ground level (AGL) to avoid disturbance.

Mitigation Measures

JADE will be working with EMAP to perform two aerial infrared (AIR) surveys. The first survey will be conducted between November 25 and December 15, and the second survey will be conducted between December 5 and December 31. In addition to AIR surveys, JADE will be using handheld and vehicle-mounted forward-looking infrared (FLIR) to locate maternal dens along any major drainages on the winter trail, snow drifts greater than 5 ft in height along the winter trail and ice roads, snow piles around each pad, and any other areas that may provide suitable snow buildup for denning polar bears. In the event a den is located, JADE will maintain a 1.6-km (1-mi) exclusion zone around the den, cease nearby activities or reduce essential activities, increase communication of personnel, and continuously monitor the den. Aircraft will be flown at a minimum of 1,500 ft AGL and will not land or take off if a bear is within 1.6 km (1 mi) of the landing/takeoff site. Additionally, work is targeted to be complete no later than July 18 prior to open-water season, which marks an increase in polar bear presence onshore.

Description of Marine Mammals in the Specified Geographic Region

Polar bears comprise 19 stocks ranging across 5 countries and 4 ecoregions that reflect the polar bear dependency on sea-ice dynamics and seasonality (Amstrup et al. 2008). Two stocks occur in the United States (Alaska) with ranges that extend to adjacent countries: Canada (SBS stock) and the Russia Federation (the Chukchi/Bering Seas [CBS] stock). The SBS stock is the only stock found in the specified geographic region. Therefore, the description below focuses on the SBS stock and general polar bear biology and behavior.

Polar Bear Biology

Polar bears are distributed throughout the ice-covered seas and adjacent coasts of the Arctic region. Polar bears typically occur at low, uneven densities throughout their circumpolar range (DeMaster and Stirling 1981, Amstrup et al. 2011, Hamilton and Derocher 2019) in areas where the sea is ice-covered for all or part of the year. They are typically most abundant on sea ice, near polynyas (*i.e.,* areas of persistent open water) and fractures in the ice, and over relatively shallow continental shelf waters with high marine productivity (Durner et al. 2004). This sea-ice habitat favors foraging for their primary prey, ringed seals (*Pusa hispida*), and other species such as bearded seals (*Erignathus barbatus*) (Thiemann et al. 2008, Cherry et al. 2011, Stirling and Derocher 2012). Polar bears prefer to remain on the sea ice year-round throughout most of their range; however, an increasing proportion of stocks are spending prolonged periods of time onshore (Rode et al. 2015, Atwood et al. 2016). While time spent on land occurs primarily in late summer and autumn (Rode et al. 2015, Atwood et al. 2016), they may be found throughout the year in the onshore and nearshore environments. Polar bear distribution in coastal habitats is often influenced by the movement of seasonal sea ice (Atwood et al. 2016, Wilson et al. 2017) and its direct and indirect effects on foraging success and, in the case of pregnant females, also dependent on the availability of suitable denning habitat (Durner et al. 2006, Rode et al. 2015, Atwood et al. 2016).

In 2008, the Service listed polar bears as threatened under the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.;* ESA), due to the loss of sea-ice habitat caused by climate change (73 FR 28212, May 15, 2008). The Service later published a final rule under section 4(d) of the ESA for the polar bear providing measures that are necessary and advisable for the conservation of polar bears (78 FR 11766, February 20, 2013). The Service designated critical habitat for polar bear populations in the United States effective January 6, 2011 (75 FR 76086, December 7, 2010) identifying geographic areas that contain features that are essential for the conservation of a threatened or endangered species and that may require special management or protection. Polar bear critical habitat units include barrier island habitat, sea-ice habitat (both described in geographic terms), and terrestrial denning habitat (a functional determination). Barrier island habitat includes coastal barrier islands and spits along Alaska's coast; it is used for denning, refuge from human disturbance, access to maternal dens and feeding habitat, and travel along the coast. Sea-ice habitat is located over the continental shelf and includes water 300 meters (m) (~984 ft) or less in depth. Terrestrial denning habitat includes lands within 32 km (~20 mi) of the northern coast of Alaska between the Canadian border and the Kavik River and within 8 km (~5 mi) between the Kavik River and Utqiaġvik. The total area designated under the ESA as critical habitat covers approximately 484,734 km² (~187,157 mi²) and is entirely within the lands and waters of the United States. A digital copy of the final rule designating critical habitat is available at *https://www.regulations.gov* in Docket No. FWS–R7–ES–2009–0042 or at: *http://www.fws.gov/r7/fisheries/mmm/polarbear/pdf/federal_register_notice.pdf.*

Polar Bear Stocks

The current total polar bear population is estimated at approximately 26,000 individuals (95 percent Confidence Interval (CI) = 22,000–31,000; Wiig et al. 2015, Regehr et al. 2016) and comprises 19 stocks

ranging across 5 countries and 4 ecoregions that reflect the polar bear dependency on sea-ice dynamics and seasonality (Amstrup et al. 2008). Two stocks occur in the United States (Alaska) with ranges that extend to adjacent countries: Canada (the Russia Federation (the Chukchi/Bering Seas [CBS] stock). In Alaska, polar bears have historically been observed as far south in the Bering Sea as St. Matthew Island and the Pribilof Islands (Ray 1971). Management and conservation concerns for the SBS and CBS polar bear stocks include sea-ice loss due to climate change, human-bear conflict, oil and gas industry activity, oil spills and contaminants, marine shipping, disease, and the potential for overharvest (USFWS 2016, Regehr et al. 2017). Most notably, reductions in physical condition, growth, and survival of polar bears have been associated with declines in sea ice (Regehr et al. 2007, Rode et al. 2014, Bromaghin et al. 2015, Lunn et al. 2016). The attrition of summer Arctic sea ice is expected to remain a primary threat to polar bear populations (Amstrup et al. 2008, Stirling and Derocher 2012), since projections indicate continued climate warming at least through the end of this century (Intergovernmental Panel on Climate Change (IPCC) 2014, Atwood et al. 2016) (see *Climate Change,* below, for further details). A detailed description of the SBS polar bear stock can be found in the Service's revised Polar Bear (*Ursus maritimus*) Stock Assessment Report announced in the **Federal Register** on June 24, 2021 (86 FR 28526). Digital copies of the revised Stock Assessment Report are available at: *https://www.fws.gov/alaska/sites/default/files/2021-06/Southern%20Beaufort%20Sea%20SAR%20Final_May%2019rev.pdf.*

Southern Beaufort Sea Stock

The SBS polar bear stock is shared between Canada and Alaska. Radio-telemetry data, combined with eartag returns from harvested bears, suggest that the SBS stock occupies a region with a western boundary near Icy Cape, Alaska (Scharf et al. 2019), and an eastern boundary near Tuktoyaktuk, Northwest Territories, Canada (Durner et al. 2018).

In 2020, the U.S. Geological Survey (USGS) produced the most recent population estimates for the Alaska portion of the SBS stock (Atwood et al. 2020), which are based on mark-recapture and collared bear data collected from the SBS stock from 2001 to 2016. The SBS stock declined from 2003 to 2006 (this was also reported by Bromaghin et al. 2015) before stabilizing from 2006 through 2015. Despite the increase in size from 2009 to 2012, low survival in 2013 appears to have offset those gains. The number of bears in the SBS stock is thought to have remained constant since the Bromaghin et al. (2015) estimate of 907 bears. This number is also supported by survival rate estimates provided by Atwood et al. (2020) that were relatively high in 2001–2003, decreased during 2004–2008, then improved in 2009, and remained high until 2015, except for much lower rates in 2012.

In Alaska during the late summer/fall period (July through November), polar bears from the SBS stock often occur along the coast and barrier islands, which serve as travel corridors, resting areas, and to some degree, foraging areas. Based on oil and gas industry (hereafter, ''Industry'') observations and coastal survey data acquired by the Service (Wilson et al. 2017), encounter rates between humans and polar bears are higher during mid-July to mid-November than in any other season. An average of 140 polar bears may occur on shore during any week during the period July through November between Utqiagvik and the Alaska-Canada border (Wilson et al. 2017). The length of time polar bears spend in these coastal habitats has been linked to sea-ice dynamics (Rode et al. 2015, Atwood et al. 2016). The remains of subsistence-harvested bowhead whales (*Balaena mysticetus*) at Cross and Barter islands provide a readily available food attractant in these areas (Schliebe et al. 2006). However, the contribution of bowhead carcasses to the diet of SBS polar bears varies annually (*e.g.,* estimated as 11–26 percent and 0–14 percent in 2003 and 2004, respectively) and by sex, likely depending on carcass and seal availability as well as sea-ice conditions (Bentzen et al. 2007).

Polar bears have no natural predators (though cannibalism is known to occur; Stirling et al. 1993). However, their life-history (*e.g.,* late maturity, small litter size, prolonged breeding interval) is conducive to low intrinsic population growth (*i.e.,* growth in the absence of human-caused mortality), which was estimated at 6 percent to 7.5 percent for the SBS stock during 2004–2006 (Hunter et al. 2010, Regehr et al. 2010). The lifespan of wild polar bears is approximately 25 years (Rode et al. 2020). Females reach sexual maturity at 3–6 years old giving birth 1 year later (Ramsay and Stirling 1988). SBS stock females typically give birth at 5 years old (Stirling et al. 1976, Lentfer and Hensel 1980). On average, SBS stock females produce litter sizes of 1.9 cubs (SD=0.5; Smith et al. 2007, 2013; Robinson 2014) at intervals that vary from 1 to 3 or more years depending on cub survival (Ramsay and Stirling 1988) and foraging conditions. For example, when foraging conditions are unfavorable, polar bears may delay reproduction in favor of survival (Derocher et al. 1992, Eberhardt 2002). The determining factor for polar bear stock growth is adult female survival (Eberhardt 1990). In general, rates above 90 percent are essential to sustain polar bear stocks (Amstrup and Durner 1995) given low cub litter survival, which was estimated at 50 percent (90 percent CI: 33–67 percent) for the SBS stock during 2001–2006 (Regehr et al. 2010). In the SBS, the probability that adult females will survive and produce cubs-of-the-year is negatively correlated with ice-free periods over the continental shelf (Regehr et al. 2007). In general, survival of cubs-of-the-year is positively related to the weight of the mother and their own weight (Derocher and Stirling 1996).

Female polar bears without dependent cubs typically breed in the spring (Amstrup 2003, Stirling et al. 2016). Pregnant females enter maternity dens between October and December (Durner et al. 2001, Amstrup 2003), and young are usually born between early December and early January (Van de Velde et al. 2003). Only pregnant females den for an extended period during the winter (Rode et al. 2018). Other polar bears may excavate temporary dens to escape harsh winter conditions; however, shelter denning is rare for Alaskan polar bear stocks (Olson et al. 2017). Maternal polar bear dens occur on barrier islands (linear features of low-elevation land adjacent to the main coastline that are separated from the mainland by bodies of water), river bank drainages, and deltas (*e.g.,* those associated with the Colville and Canning Rivers), much of the North Slope coastal plain (in particular within the 1002 Area, *i.e.,* the land designated in section 1002 of the Alaska National Interest Lands Conservation Act and that is part of the Arctic National Wildlife Refuge in northeastern Alaska; Amstrup 1993), and coastal bluffs that occur at the interface of mainland and marine habitat (Durner et al. 2006, 2013, 2020; Blank 2013; Wilson and Durner 2020).

Typically, SBS females denning on land emerge from the den with their cubs around mid-March (median emergence: March 11, Rode et al. 2018, USGS 2018) and commonly begin weaning when cubs are approximately 2.3–2.5 years old (Ramsay and Stirling 1986, Arnould and Ramsay 1994,

Amstrup 2003, Rode 2020). Cubs are born blind, with limited fat reserves, and are able to walk only after 60–70 days (Blix and Lentfer 1978, Kenny and Bickel 2005). If a female leaves a den during early denning (day of cub birth to 60 days after cub birth), cub mortality is likely to occur due to a variety of factors, including susceptibility to cold temperatures (Blix and Lentfer 1978, Hansson and Thomassen 1983, Van de Velde 2003), predation (Derocher and Wiig 1999, Amstrup et al. 2006), and mobility limitations (Lentfer 1975). Therefore, it is thought that successful denning, birthing, and rearing activities require a relatively undisturbed environment. A more detailed description of the potential consequences of disturbance to denning females can be found below in *Potential Impacts of Specified Activities on Marine Mammals: Effects to Denning Bears. Radio and satellite telemetry studies indicate that denning can occur in multiyear pack ice and on land* (Durner et al. 2020). The proportion of dens on land has increased along the Alaska region (34.4 percent in 1985–1995 to 55.2 percent in 2007–2013; Olson et al. 2017) likely in response to reductions in stable old ice, which is defined as sea ice that has survived at least one summer's melt (Bowditch 2002), increases in unconsolidated ice, and longer melt season (Fischbach et al. 2007, Olson et al. 2017). If sea-ice extent in the Arctic continues to decrease and the amount of unstable ice increases, a greater proportion of polar bears may seek to den on land (Durner et al. 2006, Fischbach et al. 2007, Olson et al. 2017).

Climate Change

Global climate change will impact the future of polar bear populations. As atmospheric greenhouse gas concentrations increase so will global temperatures (Pierrehumbert 2011, IPCC 2014) with substantial implications for the Arctic environment and its inhabitants (Harwood et al. 2001, Bellard et al. 2012, Scheffers et al. 2016, Nunez et al. 2019). The Arctic has warmed at twice the global rate (IPCC 2014), and long-term data sets show that substantial reductions in both the extent and thickness of Arctic sea-ice cover have occurred over the past 40 years (Meier et al. 2014, Frey et al. 2015). Stroeve et al. (2012) estimated that, since 1979, the minimum area of fall Arctic sea ice declined by over 12 percent per decade through 2010. Record low minimum areas of fall Arctic sea-ice extent were recorded in 2002, 2005, 2007, and 2012. Further, observations of sea ice in the Beaufort Sea have shown a trend since 2004 of sea-ice breakup earlier in the year, re-formation of sea ice later in the year, and a greater proportion of first-year ice in the ice cover (Galley et al. 2016). The overall trend of decline of Arctic sea ice is expected to continue for the foreseeable future (Stroeve et al. 2007, 73 FR 28212, May 15, 2008, Amstrup et al. 2008, Hunter et al. 2010, Overland and Wang 2013, IPCC 2014). Decline in Arctic sea ice affects Arctic species through habitat loss and altered trophic interactions. These factors may contribute to population distribution changes, population mixing, and pathogen transmission (Post et al. 2013), which further impact population health of polar bears.

For polar bears, sea-ice habitat loss due to climate change has been identified as the primary cause of conservation concern (*e.g.,* Stirling and Derocher 2012, Atwood et al. 2016, USFWS 2016). A 42 percent loss of optimal summer polar bear habitat throughout the Arctic is projected for the decade of 2045–2054 (Durner et al. 2009). A recent global assessment of the vulnerability of the 19 polar bear stocks to future climate warming ranked the SBS as one of the three most vulnerable stocks (Hamilton and Derocher 2019)). The study, which examined factors such as the size of the stock, continental shelf area, ice conditions, and prey diversity, attributed the high vulnerability of the SBS stock primarily due to deterioration of ice conditions. The SBS polar bear stock occurs within the Polar Basin Divergent Ecoregion (PBDE), which is characterized by extensive sea-ice formation during the winters and sea ice melting and pulling away from the coast during the summers (Amstrup et al. 2008). Projections show that polar bear stocks within the PBDE may be extirpated within the next 45–75 years at current rates of sea-ice declines (Amstrup et al. 2007, 2008). Atwood et al. (2016) also predicted that polar bear stocks within the PBDE will be more likely to greatly decrease in abundance and distribution as early as the 2020–2030 decade, primarily as a result of sea-ice habitat loss.

Sea-ice habitat loss affects the distribution and habitat use patterns of the SBS polar bear stock. When sea ice melts during the summer, polar bears in the PBDE may either move off the sea ice onto land for the duration of the summer or move with the sea ice as it recedes northward (Durner et al. 2009). The SBS stock, and to a lesser extent the CBS stock, are increasingly utilizing marginal habitat (*i.e.,* land and ice over less productive waters) (Ware et al. 2017). Polar bear use of Beaufort Sea coastal areas has increased during the fall open-water period (June through October). Specifically, the percentage of radio-collared adult females from the SBS stock utilizing terrestrial habitats has tripled over 15 years, and SBS polar bears arrive onshore earlier, stay longer, and leave to the sea ice later (Atwood et al. 2016). This change in polar bear distribution and habitat use has been correlated with diminished sea ice and the increased distance of the pack ice from the coast during the open-water period (*i.e.,* the less sea ice and the farther from shore the leading edge of the pack ice is, the more bears are observed onshore) (Schliebe et al. 2006, Atwood et al. 2016).

The current trend for sea ice in the SBS region will result in increased distances between the ice edge and land, likely resulting in more bears coming ashore during the open-water period (Schliebe et al. 2008). More polar bears on land for a longer period of time may increase both the frequency and the magnitude of polar bear exposure to human activities, including an increase in human–bear interactions (Towns et al. 2009, Schliebe et al. 2008, Atwood et al. 2016). Polar bears spending more time in terrestrial habitats also increases their risk of exposure to novel pathogens that are expanding north as a result of a warmer Arctic (Atwood et al. 2016, 2017). Heightened immune system activity and more infections (indicated by elevated number of white blood cells) have been reported for the SBS polar bears that summer on land when compared to those on sea ice (Atwood et al. 2017, Whiteman et al. 2019). The elevation in immune system activity represents additional energetic costs that could ultimately impact stock and individual fitness (Atwood et al. 2017, Whiteman et al. 2019). Prevalence of parasites, such as the nematode *Trichinella nativa,* in many Arctic species, including polar bears, pre-dates the recent global warming. However, parasite prevalence could increase as a result of changes in diet (*e.g.,* increased reliance on conspecific scavenging) and feeding habits (*e.g.,* increased consumption of seal muscle) associated with climate-induced reduction of hunting opportunities for polar bears (Wilson et al. 2017, Penk et al. 2021).

The continued decline in sea ice is also projected to reduce connectivity among polar bear stocks and potentially lead to the impoverishment of genetic diversity that is key to maintaining viable, resilient wildlife populations (Derocher et al. 2004, Cherry et al. 2013, Kutchera et al. 2016). The circumpolar polar bear population has been divided into six genetic clusters: The Western Polar Basin (which includes the SBS

and CBS stocks), the Eastern Polar Basin, the Western and Eastern Canadian Archipelago, and Norwegian Bay (Malenfant et al. 2016). There is moderate genetic structure among these clusters, suggesting polar bears broadly remain in the same cluster when breeding. While there is currently no evidence for strong directional gene flow among the clusters (Malenfant et al. 2016), migrants are not uncommon and can contribute to gene flow across clusters (Kutschera et al. 2016). Changing sea-ice conditions will make these cross-cluster migrations (and the resulting gene flow) more difficult in the future (Kutschera et al. 2016).

Additionally, habitat loss from decreased sea-ice extent may impact polar bear reproductive success by reducing or altering suitable denning habitat and extending the polar bear fasting season (Stirling and Derocher 2012, Rode et al. 2018, Molnár et al. 2020). Along the Alaskan region the proportion of terrestrial dens increased from 34.4 percent in 1985–1995 to 55.2 percent in 2007–2013 (Olson et al. 2017). Polar bears require a stable substrate for denning. As sea-ice conditions deteriorate and become less stable, sea-ice dens can become vulnerable to erosion from storm surges (Fischbach et al. 2007). Under favorable autumn snowfall conditions, SBS females denning on land had higher reproductive success than SBS females denning on sea ice. Factors that may influence the higher reproductive success of females with land-based dens include longer denning periods that allow cubs more time to develop, higher snowfall conditions that strengthen den integrity throughout the denning period (Rode et al. 2018), and increased foraging opportunities on land (*e.g.,* scavenging on Bowhead whale carcasses) (Atwood et al. 2016). While SBS polar bear females denning on land may experience increased reproductive success, at least under favorable snowfall conditions, it is possible that competition for suitable denning habitat on land may increase due to more female polar bears denning on shore as a result of sea-ice decline (Fischbach et al. 2007) and land-based dens may be more vulnerable to disturbance from human activities (Linnell et al. 2000).

Polar bear reproductive success, throughout the Circumpolar Region, may also be impacted by declines in sea ice through an extended fasting season (Molnár et al. 2020). By 2100, recruitment is predicted to become jeopardized in nearly all polar bear stocks if greenhouse gas emissions remain uncurbed (RCP 8.5 [Representative Concentration Pathway 8.5] scenario) as fasting thresholds are increasingly exceeded due to declines in sea ice across the Arctic circumpolar range (Molnár et al. 2020). As the fasting season increases, most of these 19 stocks, including in the SBS stock, are expected to first experience significant adverse effects on cub recruitment followed by effects on adult male survival and lastly on adult female survival (Molnár et al. 2020). Without mitigation of greenhouse gas emissions and assuming optimistic polar bear responses (*e.g.,* reduced movement to conserve energy), cub recruitment in the SBS stock has possibly been already adversely impacted since the late 1980s, while detrimental impacts on male and female survival are forecasted to possibly occur in the late 2030s and 2040s, respectively.

Extended fasting seasons are associated with poor body condition (Stirling and Derocher 2012), and a female's body condition at den entry is a critical factor that determines whether the female will produce cubs and the cubs' chance of survival during their first year (Rode et al. 2018). Additionally, extended fasting seasons will cause polar bears to depend more heavily on their lipid reserves for energy, which can release lipid-soluble contaminants, such as persistent organic pollutants and mercury, into the bloodstream and organ tissues. The increased levels of contaminants in the blood and tissues can affect polar bear health and body condition, which has implications for reproductive success and survival (Jenssen et al. 2015).

Changes in sea ice can impact polar bears by altering trophic interactions. Differences in sea-ice dynamics, such as the timing of ice formation and breakup, as well as changes in sea-ice type and concentration, may impact the distribution of polar bears and/or their prey's occurrence and reduce polar bears' access to prey. A climate-induced reduction in overlap between female polar bears and ringed seals was detected after a sudden sea-ice decline in Norway that limited the ability of females to hunt on sea ice (Hamilton et al. 2017). While polar bears are opportunistic and hunt other species, their reliance on ringed seals is prevalent across their range (Thiemann et al. 2007, 2008; Florko et al. 2020; Rode et al. 2021). Male and female polar bears exhibit differences in prey consumption. Females typically consume more ringed seals compared to males, which is likely related to more limited hunting opportunities for females (*e.g.,* prey size constraints) (McKinney et al. 2017, Bourque et al. 2020). Female body condition has been positively correlated with consumption of ringed seals, but negatively correlated with the consumption of bearded seals (Florko et al. 2020). Consequently, females are more prone to decreased foraging and reproductive success than males during years in which unfavorable sea-ice conditions limit polar bears' access to ringed seals (Florko et al. 2020).

In the SBS stock, adult female and juvenile polar bear consumption of ringed seals was negatively correlated with winter Arctic oscillation, which affects sea-ice conditions (McKinney et al. 2017). This trend was not observed for male polar bears. Instead, male polar bears consumed more bowhead whale as a result of scavenging the carcasses of subsistence-harvested bowhead whales during years with a longer ice-free period over the continental shelf. It is possible that these alterations in sea-ice conditions may limit female polar bears' access to ringed seals, and male polar bears may rely more heavily on alternative onshore food resources in the SBS region (McKinney et al. 2017). Changes in the availability and distribution of seals may influence polar bear foraging efficiency. Reduction in sea ice is expected to render polar bear foraging energetically more demanding, as moving through fragmented sea ice and open-water swimming require more energy than walking across consolidated sea ice (Cherry et al. 2009, Pagano et al. 2012, Rode et al. 2014, Durner et al. 2017). Inefficient foraging can contribute to nutritional stress and poor body condition, which can have implications for reproductive success and survival (Regehr et al. 2010).

The decline in Arctic sea ice is associated with the SBS polar bear stock spending more time in terrestrial habitats (Schliebe et al. 2008). Recent changes in female denning habitat and extended fasting seasons as a result of sea-ice decline may affect the reproductive success of the SBS polar bear stock (Stirling and Derocher 2012, Rode et al. 2018, Molnár et al. 2020). Other relevant factors that could negatively affect the SBS polar bear stock include changes in prey availability, reduced genetic diversity through limited population connectivity and/or hybridization with other bear species, increased exposure to disease and parasite prevalence and/or dissemination, impacts of human activities (oil and gas exploration/extraction, shipping, subsistence harvest, etc.) and pollution (Post et al. 2013, Hamilton and Derocher 2019). Based on the projections of sea-ice decline in the Beaufort Sea region and demonstrated impacts on SBS polar bear

utilization of sea-ice and terrestrial habitats, the Service anticipates that polar bear use of the Beaufort Sea coastal area will continue to increase during the open-water season.

Potential Impacts of the Specified Activities on Marine Mammals

Human-Polar Bear Encounters

Industry activities may affect polar bears in numerous ways. SBS polar bears are typically distributed in offshore areas associated with multiyear pack ice from mid-November to mid-July and can be found in large numbers and high densities on barrier islands, along the coastline, and in the nearshore waters of the Beaufort Sea from mid-July to mid-November. This distribution leads to a significantly higher number of human-polar bear encounters on land and at offshore structures during the open-water period (mid-July to mid-November) than at other times of the year. Because the project is located entirely on land, the remainder of this discussion will focus on human-polar bear encounters on land.

A majority of Industry's on-land bear observations occur within 2 km (1.2 mi) of the coastline; however, the location for these specified activities are primarily located outside of the coastal area. Encounters are more likely to occur during the fall at facilities on or near the coast. These facilities and associated infrastructure may act as physical barriers to polar bear movements; however, polar bears have frequently been observed crossing existing roads. Polar bear interaction plans, training, and monitoring have the potential to reduce human-polar bear encounters and the risks to bears and humans when encounters occur. Polar bear interaction plans detail the policies and procedures that the associated facilities and personnel will implement to avoid attracting and interacting with polar bears as well as minimizing impacts to the bears. Interaction plans also detail how to respond to the presence of polar bears, the chain of command and communication, and required training for personnel.

The noises, sights, and smells produced by the proposed project activities could disturb and elicit variable responses from polar bears. Noise disturbance can originate from either stationary or mobile sources. Stationary sources include construction, maintenance, repair and cleanup activities, and drilling operations. Mobile sources include aircraft traffic, ice road construction, vehicle traffic, tracked vehicles, and snowmobiles.

The potential behavioral reaction of polar bears to the specified activities can vary by activity type. Camp odors may attract polar bears, potentially resulting in human-bear encounters, intentional hazing, or possible lethal take in defense of human life. Noise generated on the ground by industrial activity may cause a behavioral (*e.g.,* escape response) or physiologic (*e.g.,* increased heart rate, hormonal response) (Harms et al. 1997, Tempel and Gutierrez 2003) response. The available studies of polar bear behavior indicate that the intensity of polar bear reaction to noise disturbance may be based on previous interactions, sex, age, and maternal status (Dyck and Baydack 2004, Anderson and Aars 2008).

Effects of Aircraft Overflights on Polar Bears

Bears near aircraft flight paths experience increased noise and visual stimuli, both have the potential to elicit a biologically significant behavioral response. Polar bears likely have acute hearing with previous sensitivities demonstrated between 1.4–22.5 kHz (tests were limited to 22.5 kHz; Nachtigall et al. 2007). This range, which is wider than that seen in humans, supports the idea that polar bears may experience temporary (called temporary threshold shift, or TTS) or permanent (called permanent threshold shift, or PTS) hearing impairment if they are exposed to high-energy sound. While species-specific TTS and PTS thresholds have not been established for polar bears, thresholds have been established for the general group ''other marine carnivores,'' which includes polar bears (Southall et al. 2019). Through a series of systematic modeling procedures and extrapolations, Southall et al. (2019) have generated modified noise exposure thresholds for in-air sound (table 1).

TABLE 1—TEMPORARY THRESHOLD SHIFT (TTS) AND PERMANENT THRESHOLD SHIFT (PTS) THRESHOLDS ESTABLISHED BY SOUTHALL ET AL. (2019) THROUGH MODELING AND EXTRAPOLATION FOR ''OTHER MARINE CARNIVORES,'' WHICH INCLUDES POLAR BEARS

[Values are weighted for other marine carnivores' hearing thresholds and given in cumulative sound exposure level (SEL_{CUM} dB re (20μPa)^{2}s in air) for impulsive and non-impulsive sounds and unweighted peak sound pressure level in air (dB re 20μPa) (impulsive sounds only).]

	TTS			PTS		
	Non-impulsive	Impulsive		Non-impulsive	Impulsive	
	SEL_{CUM}	SEL_{CUM}	Peak SPL	SEL_{CUM}	SEL_{CUM}	Peak SPL
Air	157	146	161	177	161	167

During a Federal Aviation Administration test, test aircraft produced sound at all frequencies measured AGL (50 Hz to 10 kHz) (Healy 1974). At frequencies centered at 5 kHz, jets flying at 300 m (984 ft) produced ⅓ octave band noise levels of 84 to 124 dB AGL, propeller-driven aircraft produced 75 to 90 dB AGL, and helicopters produced 60 to 70 dB AGL (Richardson et al. 1995). Thus, the frequency and level of airborne sounds typically produced by the activities associated with JADE's Request is unlikely to cause temporary or permanent hearing damage. Sound frequencies produced by aircraft will likely fall within the hearing range of polar bears (see Nachtigall et al. 2007) and will thus be audible to animals during flyovers or when operating in proximity to polar bears.

Although temporary or permanent hearing damage is not anticipated, impacts to bears near aircraft flight paths have the potential to elicit biologically significant behavioral responses from polar bears. Observations of polar bears during fall coastal surveys, which flew at much lower altitudes than typical flights, indicate that the reactions of non-denning polar bears are typically varied but limited to short-term changes in behavior ranging from no reaction to running away. Polar bears associated with dens have been shown to increase vigilance, initiate rapid movement, and even abandon dens when exposed to low-flying aircraft. Aircraft activities can impact polar bears over all seasons; however, during the summer and fall

seasons, aircraft have the potential to disturb both individuals and congregations of polar bears. These onshore polar bears spend the majority of their time resting and limiting their movements on land. Exposure to auditory and visual stimuli associated with aircraft flight paths is likely to result in changes in behavior, such as going from resting to walking or running, and, therefore, has the potential to be energetically costly. Mitigation measures, such as minimum flight elevations over polar bears and avoidance of frequently used habitat areas as well as flight restrictions around known polar bear aggregations, will be required when safe, to achieve least practicable adverse impact of the likelihood that polar bears are disturbed by aircraft.

Effects to Denning Polar Bears

The Service monitors known polar bear dens around the oilfield discovered either opportunistically or during planned surveys for tracking marked polar bears and detecting polar bear dens. However, these sites are only a small percentage of the total active polar bear dens for the SBS stock in any given year. To identify any active polar bear dens in the area, JADE has included in the Request plans to conduct AIR surveys in addition to using handheld and vehicle-mounted FLIR. If a polar bear den is located, activities are required to avoid known polar bear dens by 1.6 km (1 mi). When a previously unknown den is discovered in proximity to ongoing activities, JADE will implement mitigation measures such as the 1.6-km (1-mi) activity exclusion zone around the den and 24-hour monitoring of the site.

The responses of denning polar bears to disturbance and the consequences of these responses can vary throughout the denning process. We divide the denning period into four stages when considering impacts of disturbance: Den establishment, early denning, late denning, and post-emergence; definitions and descriptions are located in the 2021–2026 Beaufort Sea ITR (86 FR 42982, August 5, 2021).

Effects of Industry Activities on Polar Bear Prey

While some oil and gas activity on the North Slope of Alaska may impact polar bears indirectly by altering polar bears' access to their prey, primarily ringed seals and bearded seals, impacts from the specified activities will not occur offshore. Therefore, the specified activities are not anticipated to have effects on polar bear prey or their availability to access prey.

Estimated Take

Definitions of Incidental Take Under the Marine Mammal Protection Act

Below we provide definitions of potential types of take of polar bears. The Service does not anticipate and is not authorizing lethal take or Level A harassment as a part of this proposed incidental harassment authorization, nor was it included in the Request; however, the definitions of these take types are provided for context and background.

Lethal Take

Human activity may result in biologically significant impacts to polar bears. In the most serious interactions (*e.g.,* vehicle collision or running over an unknown den causing its collapse), human actions can result in polar bear mortality. We also note that, while not considered incidental, in situations where there is an imminent threat to human life, polar bears may be killed. Additionally, though not considered incidental, polar bears have been accidentally killed during efforts to deter polar bears from a work area for safety and from direct chemical exposure (81 FR 52276, August 5, 2016). Unintentional disturbance of a female polar bear by human activity during the denning season may cause the female either to abandon her den prematurely with cubs or abandon her cubs in the den before the cubs can survive on their own. Either scenario may result in the incidental lethal take of the cubs.

Level A Harassment

Human activity may result in the injury of polar bears. Level A harassment for nonmilitary readiness activities is defined as any act of pursuit, torment, or annoyance that has the potential to injure a marine mammal or marine mammal stock in the wild. Numerous actions can cause take by Level A harassment, such as creating an annoyance that separates mothers from dependent cubs (Amstrup 2003), results in polar bear mothers leaving the den early (Amstrup and Gardner 1994, Rode et al. 2018), or interrupts the nursing or resting of cubs.

Level B Harassment

Level B Harassment for nonmilitary readiness activities means any act of pursuit, torment, or annoyance that has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behaviors or activities, including, but not limited to, migration, breathing, nursing, feeding, or sheltering. Human-caused changes in behavior that disrupt biologically significant behaviors or activities for the affected animal indicate take by Level B harassment under the MMPA. Such reactions include, but are not limited to, the following:

- Fleeing (running or swimming away from a human or a human activity);
- Displaying a stress-related behavior such as jaw or lip-popping, front leg stomping, vocalizations, circling, intense staring, or salivating;
- Abandoning or avoiding preferred movement corridors such as ice floes, leads, polynyas, a segment of coastline, or barrier islands;
- Using a longer or more difficult route of travel instead of the intended path;
- Interrupting breeding, sheltering, or feeding;
- Moving away at a fast pace (adult) and cubs struggling to keep up;
- Ceasing to nurse or rest (cubs);
- Ceasing to rest repeatedly or for a prolonged period (adults);
- Loss of hunting opportunity due to disturbance of prey; or
- Any interruption in normal denning behavior that does not cause injury, den abandonment, or early departure of the family group from the den site.

This list is not meant to encompass all possible behaviors; other behavioral responses may also be indicative of Level B harassment. Relatively minor changes in behavior such as increased vigilance or a short-term change in direction of travel are not likely to disrupt biologically important behavioral patterns, and the Service does not view such minor changes in behavior as indicative of Level B harassment. It is also important to note that reactions of greater duration, frequency, or severity than contemplated in the list above could reflect take by Level A harassment.

Surface Interactions

Encounter Rate

Human-caused disturbances cannot cause take if no polar bears are present in the area of exposure. To quantify the anticipated take associated with a given activity, it is necessary to evaluate the number of polar bears anticipated to be present within the area of exposure. The best available scientific evidence for estimating polar bear prevalence near areas of industrial activities on the North Slope includes data concerning human–polar bear encounters. The most comprehensive dataset of human-polar bear encounters along the coast of Alaska consists of records of Industry encounters during activities on the North Slope submitted to the Service

under existing and previous incidental take regulations. This database is referred to as the ''LOA database'' because it aggregates data reported by the Industry to the Service pursuant to the terms and conditions of Letters of Authorization (LOA) issued under current and previous incidental take regulations (50 CFR part 18, subpart J). We have used records in the LOA database from the period 2014–2018, in conjunction with polar bear density projections for the entire coastline, to generate quantitative encounter rates in the project area. This 5-year period was used to provide metrics that reflected the most recent patterns of polar bear habitat use within the Beaufort Sea region. Each encounter record includes the date and time of the encounter, a general description of the encounter, number of bears encountered, latitude and longitude, weather variables, and the Service's take determination. If latitude and longitude were not supplied in the initial report, we georeferenced the encounter using the location description and a map of North Slope infrastructure.

Spatially Partitioning the North Slope Into ''coastal'' and ''inland'' Zones

The vast majority of SBS polar bear encounters along the Alaskan coast occur along the shore or immediately offshore (Atwood et al. 2015, Wilson et al. 2017). Thus, encounter rates for inland operations should be significantly lower than those for offshore or coastal operations. To partition the North Slope into ''coastal'' and ''inland'' zones, we calculated the distance to shore for all encounter records in the period 2014–2018 in the Service's LOA database using a shapefile of the coastline and the dist2Line function found in the R geosphere package (Geosphere Version 1.5–10, *https://cran.r-project.org/web/packages/geosphere/index.html,* accessed May 26, 2019). Linked sightings of the same bear(s) were removed from the analysis, and individual records were created for each bear encountered. However, because we were able to identify and remove only repeated sightings that were designated as linked within the database, it is likely that some repeated encounters of the same bear remained in our analysis. Of the 1,713 bears encountered from 2014 through 2018, 1,140 (66.5 percent) of the bears were offshore. While these bears were encountered offshore, the encounters were reported by onshore or island operations (*i.e.,* docks, drilling and production islands, or causeways). We examined the distribution of bears that were onshore and up to 10 km (6.2 mi) inland to determine the distance at which encounters sharply decreased (figure 2).

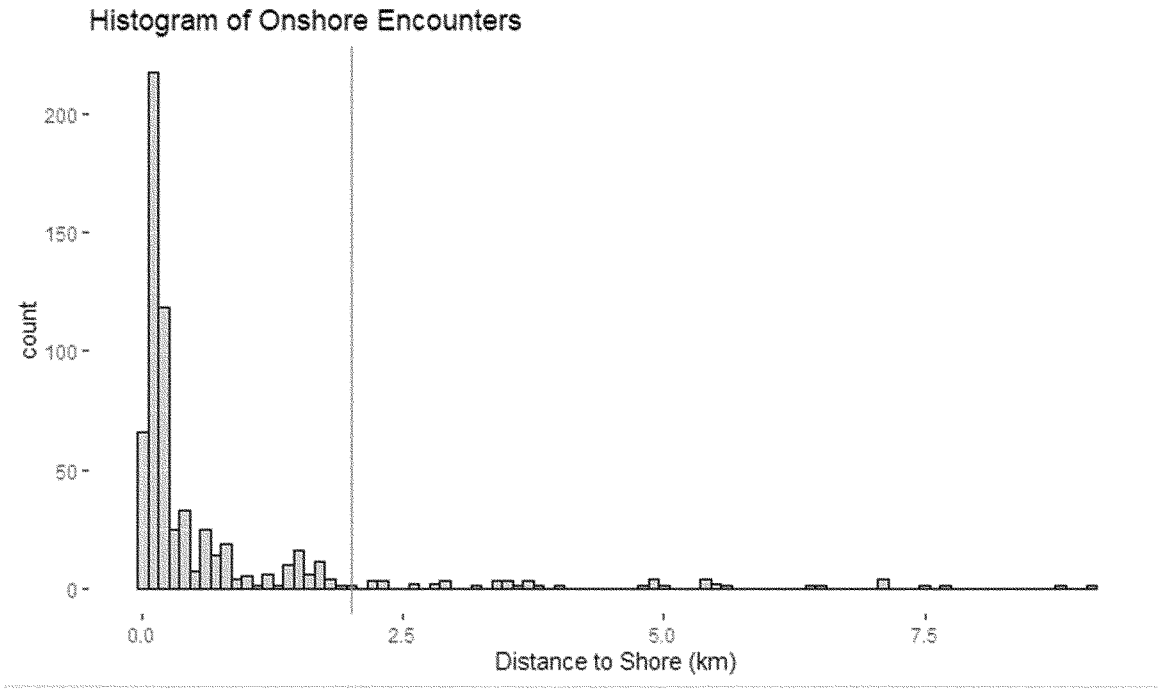

Figure 2—Distribution of onshore polar bear encounters on the North Slope of Alaska in the period 2014–2018 by distance to shore (km). The decrease in encounters was used to designate a "coastal" zone up to 2.0 km (1.2 mi) from shore and an "inland" zone greater than 2.0 km (1.2 mi) from shore.

The histogram illustrates a steep decline in human-polar bear encounters at 2 km (1.2 mi) from shore. Using this data, we divided the North Slope into the ''coastal zone,'' which includes offshore operations and up to 2 km (1.2 mi) inland, and the ''inland zone,'' which includes operations more than 2 km (1.2 mi) inland.

Dividing the Year Into Seasons

As we described in *Polar Bear Biology* above, the majority of polar bears spend the winter months on the sea ice, leading to few polar bear encounters on the shore during this season. Many of the specified activities are also seasonal, and only occur either in the winter or summer months. To develop an accurate estimate of the number of polar bear encounters that may result from the

specified activities, we divided the year into seasons of high bear activity and low bear activity using the Service's LOA database. Below is a histogram of all bear encounters from 2014 through 2018 by day of the year (Julian date). Two clear seasons of polar bear encounters can be seen: An ''open-water season'' that begins in mid-July and ends in mid-November, and an ''ice season'' that begins in mid-November and ends in mid-July. The 200th and 315th days of the year were used to delineate these seasons when calculating encounter rates (figure 3).

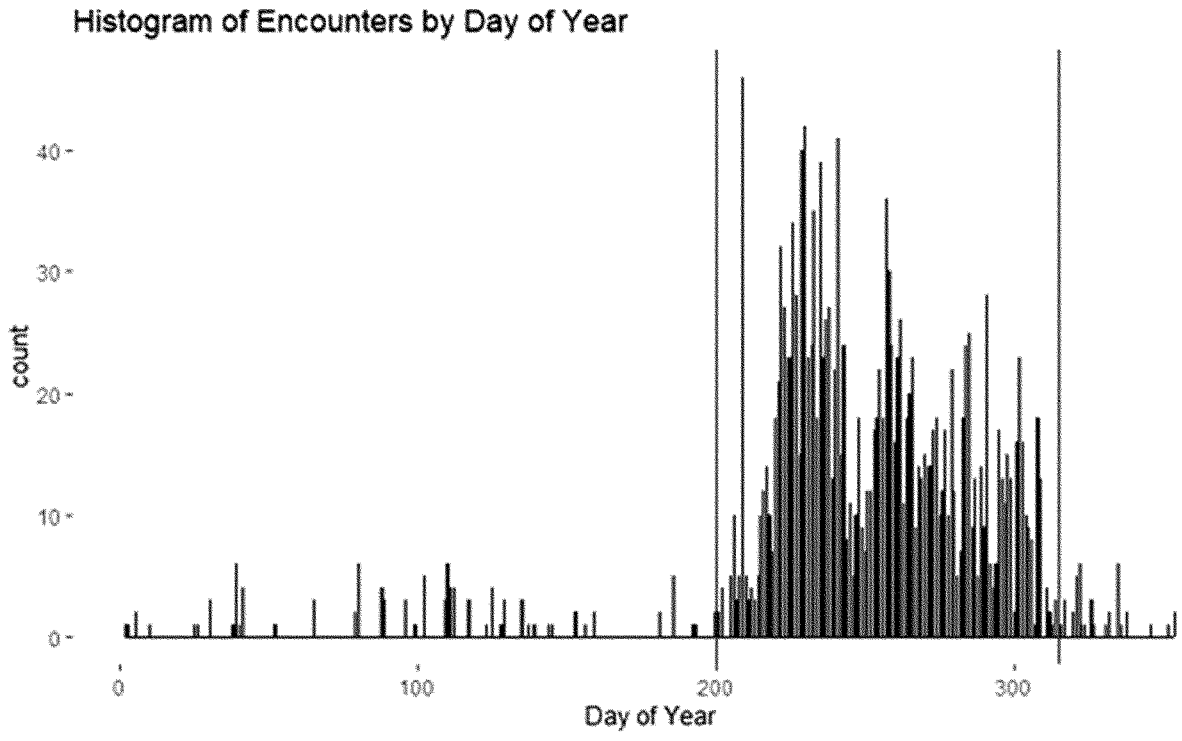

Figure 3—Distribution of polar bear encounters in the Southern Beaufort Sea and adjacent North Slope of Alaska in the period 2014–2018 by Julian day of year. Dotted lines delineate the "open" vs. "ice" seasons. Open season begins on the 200th day of the year (July 19th) and ends on the 315th day of the year (November 11th).

North Slope Encounter Rates

Encounter rates in bears/season/km² were calculated using a subset of the Industry encounter records maintained in the Service's LOA database. The following formula was used to calculate encounter rate (Equation 1):

$$\frac{Bears\ Encountered\ by\ Season}{Area\ Occupied\ (km^2)}$$

Equation 1

The subset consisted of encounters in areas that were constantly occupied year-round to prevent artificially inflating the denominator of the equation and negatively biasing the encounter rate. To identify constantly occupied North Slope locations, we gathered data from several sources. We used past LOA applications to find descriptions of projects that occurred anywhere within 2014–2018 and the final LOA reports to determine the projects that proceeded as planned and those that were never completed. Finally, we relied upon the institutional knowledge of our staff, who have worked with operators and inspected facilities on the North Slope. To determine the area around industrial facilities in which a polar bear can be seen and reported, we queried the Service LOA database for records that included the distance to an encountered polar bear. It is important to note that these values may represent the closest distance a bear came to the observer or the distance at initial contact. Therefore, in some cases, the bear may have been initially encountered farther than the distance recorded. The histogram of

these values shows a drop in the distance at which a polar bear is encountered at roughly 1.6 km (1 mi) (figure 4).

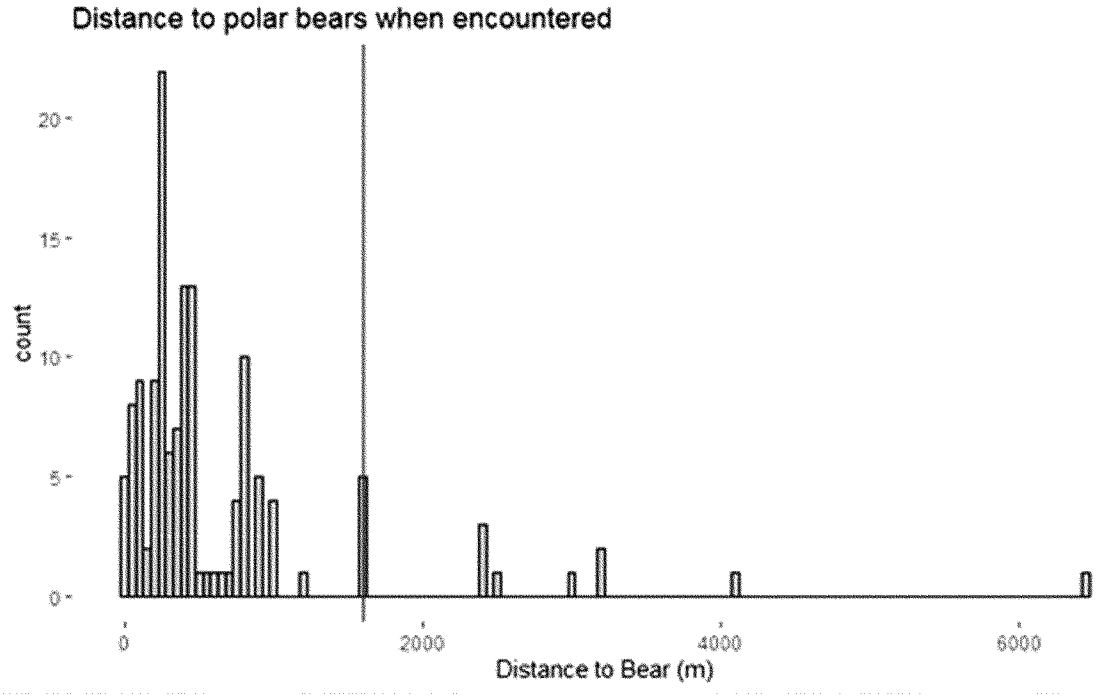

Figure 4—Distribution of polar bear encounters on the North Slope of Alaska in the period 2014–2018 by distance to bear (m).

Using this information, we buffered the 24-hour occupancy locations listed above by 1.6 km (1 mi) and calculated an overall search area for both the coastal and inland zones. The coastal and inland occupancy buffer shapefiles were then used to select encounter records that were associated with 24-hour occupancy locations, resulting in the number of bears encountered per zone. These numbers were then separated into open-water and ice seasons (table 2).

TABLE 2—SUMMARY OF ENCOUNTERS OF POLAR BEARS ON THE NORTH SLOPE OF ALASKA IN THE PERIOD 2014–2018 WITHIN 1.6 KM (1 MI) OF THE 24-HOUR OCCUPANCY LOCATIONS AND SUBSEQUENT ENCOUNTER RATES FOR COASTAL (A) AND INLAND (B) ZONES

Year	Ice season encounters	Open-water season encounters
(A) Coastal Zone (Area = 133 km^2):		
2014	2	193.
2015	8	49.
2016	4	227.
2017	7	313.
2018	13	205.
Average	6.8	197.4
Seasonal Encounter Rate	0.05 bears/km^2	1.48 bears/km^2.
(B) Inland Zone (Area = 267 km^2):		
2014	3	3.
2015	0	0.
2016	0	2.
2017	3	0.
2018	0	2.
Average	1.2	1.4.
Seasonal Encounter Rate	0.004 bears/km^2	0.005 bears/km^2.

Harassment Rate

The Level B harassment rate or the probability that an encountered bear will experience Level B harassment was calculated using the 2014–2018 dataset from the LOA database. A binary logistic regression of harassment regressed upon distance to shore was not significant (p=0.65), supporting the use of a single harassment rate for both the coastal and inland zones. However, a binary logistic regression of

harassment regressed upon day of the year was significant. This significance held when encounters were binned into either ice or open-water seasons ($p < 0.0015$).

We subsequently estimated the harassment rate for each season with a Bayesian probit regression with season as a fixed effect (Hooten and Hefley 2019). Model parameters were estimated using 10,000 iterations of a Markov chain Monte Carlo algorithm composed of Gibbs updates implemented in R (R core team 2021, Hooten and Hefley 2019). We used Normal (0,1) priors, which are uninformative on the prior predictive scale (Hobbs and Hooten 2015), to generate the distribution of open-water and ice-season marginal posterior predictive probabilities of harassment. The upper 99 percent quantile of each probability distribution can be interpreted as the upper limit of the potential harassment rate supported by our dataset (*i.e.,* there is a 99 percent chance that given the data the harassment rate is lower than this value). We chose to use 99 percent quantiles of the probability distributions to account for any negative bias that has been introduced into the dataset through unobserved harassment or variability in the interpretation of polar bear behavioral reactions by multiple observers. The final harassment rates were 0.19 during the open-water season and 0.37 during the ice season (figure 5).

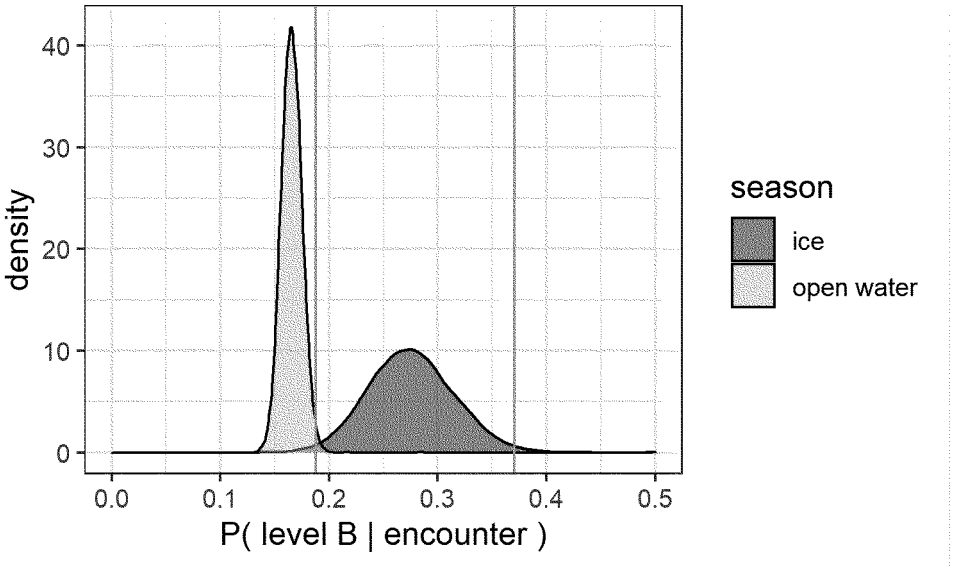

Figure 5—Estimated marginal posterior predictive probabilities from the Bayesian probit regression of Level B harassment of polar bears on the North Slope of Alaska in the period 2014–2018. Vertical gray lines correspond to the upper 99 percent quantiles for each distribution, which were used as the estimates of harassment rates.

Impact Area

As noted above, we have calculated encounter rates depending on the distance from shore and season and take rates depending on season. To properly assess the area of potential impact from the project activities, we must calculate the area affected by project activities to such a degree that harassment is possible. This is sometimes referred to as a zone or area of influence. Behavioral response rates of polar bears to disturbances are highly variable, and data to support the relationship between distance to bears and disturbance is limited. Dyck and Baydack (2004) found sex-based differences in the frequencies of vigilant bouts of polar bears in the presence of vehicles on the tundra. However, in their summary of polar bear behavioral response to ice-breaking vessels in the Chukchi Sea, Smultea et al. (2016) found no difference between reactions of males, females with cubs, or females without cubs. During the Service's coastal aerial surveys, 99 percent of polar bears that responded in a way that indicated possible Level B harassment (polar bears that were running when detected or began to run or swim in response to the aircraft) did so within 1.6 km (1 mi), as measured from the ninetieth percentile horizontal detection distance from the flight line. Similarly, Andersen and Aars (2008) found that female polar bears with cubs (the most conservative group observed) began to walk or run away from approaching snowmobiles at a mean distance of 1,534 m (0.95 mi). Thus, while future research into the reaction of polar bears to anthropogenic disturbance may indicate a different zone of potential impact is appropriate, the current literature suggests 1.6 km (1.0 mi) will likely encompass the majority of polar bear harassment events.

Correction Factor

While the locations that were used to calculate encounter rates are thought to have constant human occupancy, it is possible that bears may be in the vicinity of industrial infrastructure and not be noticed by humans. These unnoticed bears may also experience Level B harassment. To determine whether our calculated encounter rate should be corrected for unnoticed bears, we compared our encounter rates to Wilson et al.'s (2017) weekly average polar bear estimates along the northern coast of Alaska and the South Beaufort Sea.

Wilson et al.'s weekly average estimate of polar bears across the coast was informed by Service-conducted aerial surveys in the period 2000–2014

and supplemented by daily counts of polar bears in three high-density barrier islands (Cross, Barter, and Cooper Islands). Using a Bayesian hierarchical model, the authors estimated 140 polar bears would be along the coastline each week between the months of August and October. These estimates were further partitioned into 10 equally sized grids along the coast. Grids 4–7 overlap the SBS area, including the PBU and PTU in which the specified activities are proposed to occur. Grid 6 was estimated to account for 25 percent of the weekly bear estimate (35 bears); however, 25 percent of the bears in grid 6 were located on Cross Island. Grids 5 and 7 were estimated to contain 7 bears each, weekly. Using raw aerial survey data, we calculated the number of bears per km of surveyed mainland and number of bears per km of surveyed barrier islands for each Service aerial survey from 2010 through 2014 to determine the proportion of bears on barrier islands versus the mainland. On average, 1.7 percent, 7.2 percent, and 14 percent of bears were sighted on the mainland in grids 5, 6, and 7, respectively.

While linked encounter records in the LOA database were removed in earlier formatting, it is possible that a single bear may be the focus of multiple encounter records, particularly if the bear moves between facilities operated by different entities. To minimize repeated sightings, we designated a single industrial infrastructure location in each grid: Oliktok Point in grid 5, West Beach in grid 6, and Point Thomson's central pad in grid 7. These locations were determined in earlier analyses to have constant 24-hour occupancy; thus, if a polar bear were within the viewing area of these facilities, it must be reported as a condition of each entity's LOA.

Polygons of each facility were buffered by 1.6 km (1 mi) to account for the industrial viewing area (see above) and then clipped by a 400-m (0.25-mi) buffer around the shoreline to account for the area in which observers were able to reliably detect polar bears in the Service's aerial surveys (*i.e.,* the specific area to which the Wilson et al.'s model predictions applied). Industrial encounters within this area were used to generate the average weekly number of polar bears from August through October. Finally, we divided these numbers by area to generate average weekly bears/km^2 and multiplied this number by the total coastal Service aerial survey area. The results are summarized in table 3.

TABLE 3—COMPARISON OF POLAR BEAR ENCOUNTERS TO NUMBER OF POLAR BEARS PROJECTED BY WILSON ET AL. 2017 AT DESIGNATED POINT LOCATIONS ON THE COAST OF THE NORTH SLOPE OF ALASKA

	Grid 5	Grid 6	Grid 7
Total coastline viewing area (km^2)	34	45	33.4
Industry viewing area (km^2)	0.31	0.49	1.0
Proportion of coastline area viewed by point location	0.009	0.011	0.030
Average number of bears encountered August–October at point location	3.2	4.6	28.8
Number of weeks in analysis	13	13	13
Average weekly number of bears *reported* at point location	0.246	0.354	2.215
Average weekly number of bears projected in grid	7	26	7
Average weekly number of bears *projected* for point location	0.064	0.283	0.210

These comparisons show a greater number of industrial sightings than would be estimated by the Wilson et al. 2017 model. There are several potential explanations for higher industrial encounters than projected by model results. Polar bears may be attracted to industrial infrastructure, the encounters documented may be multiple sightings of the same bear, or specifically for the Point Thomson location, higher numbers of polar bears may be travelling past the pad to the Kaktovik whale carcass piles. However, because the number of polar bears estimated within the point locations is lower than the average number of industrial sightings, these findings cannot be used to create a correction factor for industrial encounter rate. To date, the data needed to create such a correction factor (*i.e.,* spatially explicit polar bear densities across the North Slope) have not been generated.

Estimated Harassment

We estimated Level B harassment using the spatio-temporally specific encounter rates and temporally specific take rates derived above in conjunction with JADE supplied spatially and temporally specific data. Table 4 provides the definition for each variable used in the take formulas.

TABLE 4—DEFINITIONS OF VARIABLES USED IN TAKE ESTIMATES OF POLAR BEARS ON THE COAST OF THE NORTH SLOPE OF ALASKA

Variable	Definition
B_{es}	bears encountered in an area of interest for the entire season.
a_c	coastal exposure area.
a_i	inland exposure area.
r_o	occupancy rate.
e_{ci}	coastal ice season bear-encounter rate in bears/season.
e_{ii}	inland ice season bear-encounter rate in bears/season.
t_i	ice season harassment rate.
B_t	number of estimated Level B harassment events.

The variables defined above were used in a series of formulas to ultimately estimate the total harassment from surface-level interactions. Encounter rates were originally calculated as bears encountered per square kilometer per season (see North Slope Encounter Rates above). As a part of their Request, JADE provided the Service with digital geospatial files and crew shift information that was used to determine the maximum expected human occupancy (*i.e.,* rate of occupancy (r_o)) for each phase of the project (*e.g.,* construction of ice roads, construction of ice pads, ice road maintenance, drilling, etc.). Using the buffer tool in ArcGIS, we created a spatial file of a 1.6-km (1-mi) buffer around all proposed structures. The areas of impact were then clipped by coastal and inland zone shapefiles to determine the coastal areas of impact (a_c) and inland areas of impact (a_i) for each activity category. We then used spatial files of the coastal and inland zones to determine the area in coastal versus inland zones for each occupancy percentage.

Impact areas were multiplied by the appropriate encounter rate to obtain the number of bears expected to be encountered in an area of interest per season (B_{es}). The equation below (Equation 2) provides an example of the calculation of bears encountered in the

ice season for an area of interest in the coastal zone.

$$B_{es} = a_c * e_{ci}$$

Equation 2

To generate the number of estimated Level B harassments for each area of interest, we multiplied the number of bears in the area of interest per season by the proportion of the season the area is occupied, the rate of occupancy, and the harassment rate (Equation 3).

$$B_t = B_{es} * S_p * r_o * t_i$$

Equation 3

Aircraft Activities

Aircraft activities are proposed to take place only during cleanup activities lasting early- to mid-July. The proposed aircraft activity would be spatially limited, occur prior to the start of the open-water season (July 19), and be subject to mitigation measures proposed by JADE. Analyses of previous projects of a similar nature and location, but larger extents, estimated polar bear takes by harassment to be less than 0.0003 polar bears. Given this information, the Service has determined that impacts would be negligible and further analysis is not warranted.

Methods for Modeling the Effects of Den Disturbance

Case Studies Analysis

To assess the likelihood and degree of exposure and predict probable responses of denning polar bears to activities proposed in JADE's Request, we characterized, evaluated, and prioritized a series of rules and definitions towards a predictive model based on knowledge of published and unpublished information on polar bear denning ecology, behavior, and cub survival. Contributing information came from literature searches in several major research databases and data compiled from polar bear observations submitted by the Industry. We considered all available scientific and observational data we could find on polar bear denning behavior and effects of disturbance.

From these sources, we identified 57 case studies representing instances where polar bears at a maternal den may have been exposed to human activities. For each den, we considered the four denning periods separately, and for each period, determined whether adequate information existed to document whether (1) the human activity met our definition of an exposure and (2) the response of the polar bear(s) could be classified according to our rules and definitions. From these 57 dens, 80 denning period-specific events met these criteria. For each event, we classified the type and frequency (*i.e.,* discrete or repeated) of the exposure, the response of the polar bear(s), and the level of take associated with that response. From this information, we calculated the probability that a discrete or repeated exposure would result in each possible level of take during each denning period, which informed the probabilities for outcomes in the simulation model (table 5).

TABLE 5—PROBABILITY FOR EACH POSSIBLE LEVEL OF TAKE BASED ON THE 57 CASE STUDIES FROM A DISCRETE OR REPEATED EXPOSURE DURING EACH DENNING PERIOD

Exposure type	Period	None	Level B	Non-serious Level A	Serious Level A	Lethal
Discrete	Den Establishment	0.400	0.600	*NA*	*NA*	*NA*
	Early Denning	1.000	0.000	*NA*	*NA*	0.000
	Late Denning	0.091	0.000	*NA*	0.909	0.000
	Post-emergence	0.000	0.000	0.750	*NA*	0.250
Repeated	Den Establishment	1.000	0.000	*NA*	*NA*	*NA*
	Early Denning	0.800	0.000	*NA*	*NA*	0.200
	Late Denning	0.708	0.000	*NA*	0.292	0.000
	Post-emergence	0.000	0.267	0.733	*NA*	0.000

Case Study Analysis Definitions

Below, we provide definitions for terms used in this analysis, a general overview of denning chronology and periods (details are provided in the *Potential Impacts of Specified Activities on Marine Mammals: Effects to Denning Polar Bears*), and the rules established for using the case studies to inform the model.

Exposure and Response Definitions

Exposure: Any human activity within 1.6 km (1 mi) of a polar bear den site. In the case of aircraft, an overflight within 457 m (0.3 mi) above ground level.

Discrete exposure: An exposure that occurs only once and of short duration (<30 minutes). It can also be a short-duration exposure that happens repeatedly but that is separated by sufficient time that exposures can be treated as independent (*e.g.,* aerial pipeline surveys that occur weekly).

Repeated exposure: An exposure that occurs more than once within a time period where exposures cannot be considered independent or an exposure that occurs due to continuous activity during a period of time (*e.g.,* traffic along a road, or daily visits to a well pad).

Response probability: The probability that an exposure resulted in a response by denning polar bears.

We categorized each exposure into categories based on polar bear response:

- *No response:* No observed or presumed behavioral or physiological response to an exposure.
- *Likely physiological response:* An alteration in the normal physiological function of a polar bear (*e.g.,* elevated heart rate or stress hormone levels) that is typically unobservable but is likely to occur in response to an exposure.
- *Behavioral response:* A change in behavior in response to an exposure. Behavioral responses can range from biologically insignificant (*e.g.,* a resting bear raising its head in response to a vehicle driving along a road) to substantial (*e.g.,* cub abandonment) and concomitant levels of take vary accordingly.

Timing Definitions

Entrance date: The date a female first enters a maternal den after excavation is complete.

Emergence date: The date a maternal den is first opened and a bear is exposed directly to external conditions. Although a bear may exit the den completely at emergence, we considered even partial-body exits (*e.g.,* only a bear's head protruding above the surface of the snow) to represent emergence in order to maintain consistency with dates derived from temperature sensors on collared bears (*e.g.,* Rode et al. 2018). For dens located near regularly occurring human activity, we considered the first day a bear was observed near a den to be the emergence date unless other data were available to inform emergence dates (*e.g.,* GPS collar data).

Departure date: The date when bears leave the den site to return to the sea ice. If a bear leaves the den site after a disturbance but later returns, we considered the initial movement to be the departure date.

Definition of Various Denning Periods

Den establishment period: Period of time between the start of maternal den excavation and the birth of cubs. Unless evidence indicates otherwise, all dens that are excavated by adult females in the fall or winter are presumed to be maternal dens. In the absence of other information, this period is defined as denning activity prior to December 1 (*i.e.,* estimated earliest date cubs are likely present in dens (Derocher et al. 1992, Van de Velde et al. 2003)).

Early denning period: Period of time from the birth of cubs until they reach 60 days of age and are capable of surviving outside the den. In the absence of other information, this period is defined as any denning activity occurring between December 1 and February 13 (*i.e.,* 60 days after December 15 the estimated average date of cub birth; Messier et al. 1994, Van de Velde et al. 2003).

Late denning period: Period of time between when cubs reach 60 days of age and den emergence. In the absence of other information, this period is defined as any denning activity occurring between February14 and den emergence.

Post-emergence period: Period of time between den emergence and den site departure. We considered a ''normal'' duration at the den site between emergence and departure to be greater than or equal to 8 days and classified departures that occurred post emergence ''early'' if they occurred less than 8 days after emergence.

Descriptions of Potential Outcomes

Cub abandonment: Occurs when a female leaves all or part of her litter, either in the den or on the surface, at any stage of the denning process. We classified events where a female left her cubs but later returned (or was returned by humans) as cub abandonment.

Early emergence: Den emergence that occurs as the result of an exposure (see 'Rules' below).

Early departure: Departure from the den site post-emergence that occurs as the result of an exposure (see 'Rules' below).

Predictive Model Rules for Determining Den Outcomes and Assigning Take

- We considered any exposure in a 24-hour period that did not result in a Level A harassment or lethal take to potentially be a Level B harassment if a behavioral response was observed. However, multiple exposures do not result in multiple Level B harassments unless the exposures occurred in two different denning periods.
- If comprehensive dates of specific exposures are not available and daily exposures were possible (*e.g.,* the den was located within 1.6 km [1 mi] of an ice road), we assumed exposures occurred daily.
- In the event of an exposure that resulted in a disturbance to denning bears, take was assigned for each bear (*i.e.,* female and each cub) associated with that den. Whereas assigned take for cubs could range from Level B harassment to lethal take, for adult females only Level B harassment was possible.
- In the absence of additional information, we assumed dens did not contain cubs prior to December 1, but did contain cubs on or after December 1.
- If an exposure occurred and the adult female subsequently abandoned her cubs, we assigned a lethal take for each cub.
- If an exposure occurred during the early denning period and bears emerged from the den before cubs reached 60 days of age, we assigned a lethal take for each cub. In the absence of information about cub age, a den emergence that occurred between December 1 and February 13 was considered to be an early emergence and resulted in a lethal take of each cub.
- If an exposure occurred during the late denning period (*i.e.,* after cubs reached 60 days of age) and bears emerged from the den before their intended (*i.e.,* undisturbed) emergence date, we assigned a serious injury Level A harassment take for each cub. In the absence of information about cub age and intended emergence date (which was known only for simulated dens), den emergences that occurred between (and including) February 14 and March 14 were considered to be early emergences and resulted in a non-serious-injury Level A harassment take of each cub. If a den emergence

occurred after March 14 but was clearly linked to an exposure (*e.g.,* bear observed emerging from the den when activity initiated near the den), we considered the emergence to be early and resulted in a serious-injury Level A harassment take of each cub.

- For dens where emergence was not classified as early, if an exposure occurred during the post-emergence period and bears departed the den site prior to their intended (*i.e.,* undisturbed) departure date, we assigned a non-serious-injury Level A harassment take for each cub. In the absence of information about the intended departure date (which was known only for simulated dens), den site departures that occurred less than 8 days after the emergence date were considered to be early departures and resulted in a non-serious-injury Level A harassment take of each cub.

Den Simulation

We simulated dens across the entire North Slope of Alaska, ranging from the areas identified as denning habitat (Durner et al. 2006, 2013; Blank 2013) contained within the National Petroleum Reserve–Alaska (NPRA) in the west to the Canadian border in the east. While JADE's Request does not include activity inside the Arctic Refuge, we still simulated dens in that area to ensure that any activities directly adjacent to the refuge that might impact denning bears inside the refuge would be captured. To simulate dens on the landscape, we relied on the estimated number of dens in three different regions of northern Alaska provided by Atwood et al. (2020). These included the NPRA, the area between the Colville and Canning Rivers (CC), and Arctic Refuge. The mean estimated number of dens in each region during a given winter were as follows: 12 dens (95 percent CI: 3–26) in the NPRA, 26 dens (95 percent CI: 11–48) in the CC region, and 14 dens (95 percent CI: 5–30) in the Arctic Refuge (Atwood et al. 2020). For each iteration of the model (described below), we drew a random sample from a gamma distribution for each of the regions based on the above parameter estimates, which allowed uncertainty in the number of dens in each area to be propagated through the modeling process. Specifically, we used the method of moments (Hobbs and Hooten 2015) to develop the shape and rate parameters for the gamma distributions as follows: NPRA (122/5.82, 12/5.82), CC (262/9.52, 26/9.52), and Arctic Refuge (142/6.32, 14/6.32).

Because not all areas in northern Alaska are equally used for denning and some areas do not contain the requisite topographic attributes required for sufficient snow accumulation for den excavation, we did not randomly place dens on the landscape. Instead, we followed a similar approach to that used by Wilson and Durner (2020) with some additional modifications to account for differences in denning ecology in the CC region related to a preference to den on barrier islands and a general (but not complete) avoidance of actively used industrial infrastructure. Using the USGS polar bear den catalogue (Durner et al. 2020), we identified polar bear dens that occurred on land in the CC region and that were identified either by GPS-collared bears or through systematic surveys for denning bears (Durner et al. 2020). This resulted in a sample of 37 dens of which 22 (*i.e.,* 60 percent) occurred on barrier islands. For each iteration of the model, we then determined how many of the estimated dens in the CC region occurred on barrier islands versus the mainland.

To accomplish this, we first took a random sample from a binomial distribution to determine the expected number of dens from the den catalog (Durner et al. 2020) that should occur on barrier islands in the CC region during that given model iteration; n_{barrier}=Binomial(37, 22/37), where 37 represents the total number of dens in the den catalogue (Durner et al. 2020) in the CC region suitable for use (as described above) and 22/37 represents the observed proportion of dens in the CC region that occurred on barrier islands. We then divided n_{barrier} by the total number of dens in the CC region suitable for use (*i.e.,* 37) to determine the proportion of dens in the CC region that should occur on barrier islands (*i.e.,* p_{barrier}). We then multiplied p_{barrier} with the simulated number of dens in the CC region (rounded to the nearest whole number) to determine how many dens were simulated to occur on barrier islands in the region.

In the NPRA, the den catalogue (Durner et al. 2020) data indicated that two dens occurred outside of defined denning habitat (Durner et al. 2013), so we took a similar approach as with the barrier islands to estimate how many dens occur in areas of the NPRA with the den habitat layer during each iteration of the model; n_{habitat}~Binomial(15, 13/15), where 15 represents the total number of dens in NPRA from the den catalogue (Durner et al. 2020) suitable for use (as described above), and 13/15 represents the observed proportion of dens in NPRA that occurred in the region with den habitat coverage (Durner et al. 2013). We then divided n_{habitat} by the total number of dens in NPRA from the den catalogue (*i.e.,* 15) to determine proportion of dens in the NPRA region that occurred in the region of the den habitat layer (p_{habitat}). We then multiplied p_{habitat} with the simulated number of dens in NPRA (rounded to the nearest whole number) to determine the number of dens in NPRA that occurred in the region with the den habitat layer. Because no infrastructure exists and no activities are proposed to occur in the area of NPRA without the den habitat layer, we only considered the potential impacts of activity to those dens simulated to occur in the region with denning habitat identified (Durner et al. 2013).

To account for the potential influence of industrial activities and infrastructure on the distribution of polar bear selection of den sites, we again relied on the subset of dens from the den catalogue (Durner et al. 2020) discussed above. We further restricted the dens to only those occurring on the mainland because no permanent infrastructure occurred on barrier islands with identified denning habitat (Durner et al. 2006). We then determined the minimum distance to permanent infrastructure that was present when the den was identified. This led to an estimate of a mean minimum distance of dens to infrastructure being 21.59 km (SD=16.82). From these values, we then parameterized a gamma distribution: Gamma (21.592/16.822, 21.59/16.822). We then obtained 100,000 samples from this distribution and created a discretized distribution of distances between dens and infrastructure. We created 2.5-km intervals between 0 and 45 km, and one bin for areas greater than 45 km from infrastructure and determined the number of samples that occurred within each distance bin. We then divided the number of samples in each bin by the total number of samples to determine the probability of a simulated den occurring in a given distance bin. The choice of 2.5 km for distance bins was based on a need to ensure that kernel density grid cells occurred in each distance bin.

To inform where dens are most likely to occur on the landscape, we developed a kernel density map by using known den locations in northern Alaska identified either by GPS-collared bears or through systematic surveys for denning bears (Durner et al. 2020). To approximate the distribution of dens, we used an adaptive kernel density estimator (Terrell and Scott 1992) applied to

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observed den locations, which took the form

$$f(s) \propto \theta n \sum_{ni} k(s - s_i h(s)) f\mathbf{s} \propto \theta n \sum_{ink} \mathbf{s} - \boldsymbol{s}_i h\mathbf{s},$$ where the adaptive bandwidth

$$h(s) = (\beta_0 + \beta_1 I(s_i \in M) I(s \in M)) \beta_2 h\boldsymbol{s} = \beta 0 + \beta 1 I\boldsymbol{s} i \in \mathcal{M} I\boldsymbol{s} \in \mathcal{M} \beta 2$$

for the location of the *i*th den and each location

$$s\mathbf{s}$$

in the study area. The indicator functions allowed the bandwidth to vary abruptly between the mainland

$$M\mathcal{M}$$

and barrier islands. The kernel *k* was the Gaussian kernel, and the parameters

$$\theta, \beta_0, \beta_1, \beta_2 \theta, \beta 0, \beta 1, \beta 2$$

were chosen based on visual assessment so that the density estimate approximated the observed density of dens and our understanding of likely den locations in areas with low sampling effort.

The kernel density map we used for this analysis differs slightly from the version used in previous analyses, specifically our differentiation of barrier islands from mainland habitat. We used this modified version because previous analyses did not require us to consider denning habitat in the CC region, which has a significant amount of denning that occurs on barrier islands compared to the other two regions. If barrier islands were not differentiated for the kernel density estimate, density from the barrier island dens would spill over onto the mainland, which was deemed to be biologically unrealistic given the clear differences in den density between the barrier islands and the mainland in the region. We restricted the distance to infrastructure component to only the CC region because it is the region that contains the vast majority of oil and gas infrastructure and has had some form of permanent industrial infrastructure present for more than 50 years.

To simulate dens on the landscape, we first sampled in which kernel grid cell a den would occur based on the underlying relative probability (figure 6) within a given region using a multinomial distribution. Once a cell was selected, the simulated den was randomly placed on the denning habitat (Durner et al. 2006, 2013; Blank 2013) located within that grid cell. For dens being simulated on mainland in the CC region, an additional step was required. We first assigned a simulated den a distance bin using a multinomial distribution of probabilities of being located in a given distance bin based on the discretized distribution of distances described above. Based on the distance to infrastructure bin assigned to a simulated den, we subset the kernel density grid cells that occurred in the same distance bin and then selected a grid cell from that subset based on their underlying probabilities using a multinomial distribution. Then, similar to other locations, a den was randomly placed on denning habitat within that grid cell.

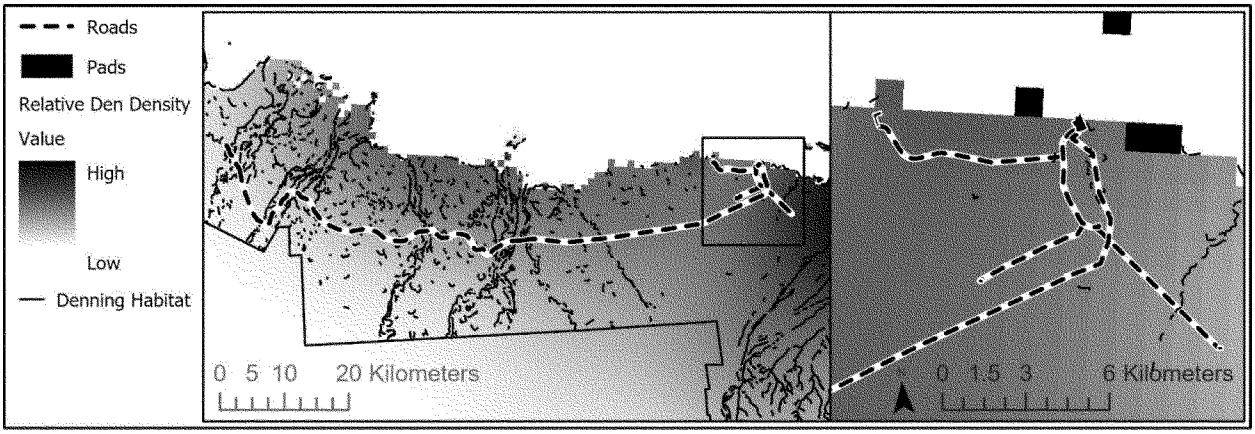

Figure 6—Depiction of the proposed project area on the North Slope of Alaska with the underlying relative density of polar bear dens and potential polar bear denning habitat as identified by Durner et al. (2006, 2013) and Blank (2013).

For each simulated den, we assigned dates of key denning events: Den entrance, birth of cubs, when cubs reached 60 days of age, den emergence, and departure from the den site after emergence. These represent the chronology of each den under undisturbed conditions. We selected the entrance date for each den from a normal distribution parameterized by entrance dates of radio-collared bears in the SBS subpopulation that denned on land included in Rode et al. (2018) and published in USGS (2018; *n*=52, mean=11 November, SD=18 days). These data were restricted to those dens with both an entrance and emergence date identified and where a bear was in the den for greater than or equal to 60 days to reduce the chances of including non-maternal bears using shelter dens. Sixty days represents the minimum age of cubs before they have a chance of survival outside of the den. Thus, periods less than 60 days in the den have a higher chance of being shelter dens.

We truncated this distribution to ensure that all simulated dates occurred within the range of observed values (*i.e.,* September 12 to December 22) identified in USGS (2018) to ensure that entrance dates were not simulated during biologically unreasonable periods given that the normal distribution allows some probability (albeit small) of dates being substantially outside a biologically reasonable range. We selected a date of birth for each litter from a normal distribution with the mean set to ordinal date 348 (*i.e.,* December 15) and standard deviation of 10, which allowed the 95 percent CI to approximate the range of birth dates (*i.e.,* December 1 to January 15) identified in the peer-reviewed literature (Messier et al. 1994, Van de Velde et al. 2003). We ensured that simulated birth dates occurred after simulated den entrance dates. We selected the emergence date as a random draw from an asymmetric Laplace distribution with parameters μ=81.0, σ=4.79, and p=0.79 estimated from the empirical emergence dates in Rode et al. (2018) and published in USGS (2018, n=52) of radio-collared bears in the SBS stock that denned on land using the mleALD function from package 'ald' (Galarzar and Lachos 2018) in program R (R Core Development Team 2021). We constrained simulated emergence dates to occur within the range of observed emergence dates (January 9 to April 9, again to constrain dates to be biologically realistic) and to not occur until after cubs were 60 days old.

Finally, we assigned the number of days each family group spent at the den site post-emergence based on values reported in three behavioral studies, Smith et al. (2007, 2013) and Robinson (2014), which monitored dens immediately after emergence (n=25 dens). Specifically, we used the mean (8.0) and SD (5.5) of the dens monitored in these studies to parameterize a gamma distribution using the method of moments (Hobbs and Hooten 2015) with a shape parameter equal to 8.02/5.52 and a rate parameter equal to 8.0/5.52; we selected a post-emergence, pre-departure time for each den from this distribution. We restricted time at the den post emergence to occur within the range of times observed in Smith et al. (2007, 2013) and Robinson (2014) (*i.e.,* 2–23 days, again to ensure biologically realistic times spent at the den site were simulated). Additionally, we assigned each den a litter size by drawing the number of cubs from a multinomial distribution with probabilities derived from litter sizes (n=25 litters) reported in Smith et al. (2007, 2013) and Robinson (2014).

Because there is some probability that a female naturally emerges with zero cubs, we also wanted to ensure this scenario was captured. It is difficult to parameterize the probability of litter size equal to zero because it is rarely observed. We, therefore, assumed that dens in the USGS (2018) dataset that had denning durations less than the shortest den duration where a female was later observed with cubs (*i.e.,* 79 days) had a litter size of zero. There were only three bears in the USGS (2018) data that met this criteria, leading to an assumed probability of a litter size of zero at emergence being 0.07. We, therefore, assigned the probability of 0, 1, 2, or 3 cubs as 0.07, 0.15, 0.71, and 0.07, respectively.

Infrastructure and Human Activities

The model developed by Wilson and Durner (2020) provides a template for estimating the level of potential impact to denning polar bears of specified activities while also considering the natural denning ecology of polar bears in the region. The approach developed by Wilson and Durner (2020) also allows for the incorporation of uncertainty in both the metric associated with denning bears and in the timing and spatial patterns of specified activities when precise information on those activities is unavailable. Below we describe the

different sources of potential disturbance we considered within the model. We considered infrastructure and human activities only within the area of proposed activity in the IHA Request. However, given that activity on the border of this region could still affect dens falling outside of the area defined in the IHA Request, we also considered the impacts to denning bears within a 1-mile buffer outside of the proposed activity area.

Roads and Pads

We obtained shapefiles of existing road and pad infrastructure associated with industrial activities from JADE. Each attribute in the shapefiles included a monthly occupancy rate that ranged from zero to one. For this analysis, we assumed that any road or pad with occupancy greater than zero for a given month had the potential for human activity during the entire month unless otherwise noted.

Ice Roads and Tundra Travel

We obtained shapefiles of proposed ice roads, tundra travel routes, and ice pads from JADE. We also received information on the proposed start and end dates for ice roads and tundra routes each winter from JADE with activity anticipated to occur at least daily along each.

Aerial Infrared Surveys

Based on JADE's Request, we assumed that all permanent infrastructure (*i.e.,* roads and pads) and ice roads would receive two AIR surveys of polar bear den habitat within 1.6 km (1 mi) of those features in the winter of 2021. The first survey would occur between November 25 and December 15, and the second survey would occur between December 5 and December 31. During each iteration of the model, the AIR surveys were randomly assigned a probability of detecting dens. Two studies (Smith et al. 2020, Woodruff et al. in prep) have been conducted since Wilson and Durner (2020) was published that require an updated approach. The study by Woodruff et al. (in prep) considered the probability of detecting heat signatures from artificial polar bear dens. They did not find a relationship between den snow depth and detection and estimated a mean detection rate of 0.24. A recent study by Smith et al. (2020) estimated that the detection rate for actual polar bear dens in northern Alaska was 0.45 and also did not report any relationship between detection and den snow depth. Because the study by Wilson and Durner (2020) reported detection probability only for dens with less than 100 cm snow depth, we needed to correct it to also include those dens with greater than 100 cm snow depth. Based on the distribution of snow depths used by Wilson and Durner (2020) derived from data in Durner et al. (2003), we determined that 24 percent of dens have snow depths greater than 100 cm. After taking these into account, the overall detection probability from Wilson and Durner (2020) including dens with snow depths greater than 100 cm was estimated to be 0.54. This led to a mean detection of 0.41 and standard deviation of 0.15 across the three studies. We used these values, and the method of moments (Hobbs and Hooten 2015), to inform a Beta distribution *i.e.,* Beta $(0.41_2 - 0.41_3 - 0.41 \times 0.1539_2 0.1539_2, 0.41 - 2 \times 0.41_2 + 0.41_3 - 0.1539_2 + 0.41 \times 0.1539_2 0.1539_2)$ *Beta* $0.412 - 0.413 - 0.41 \times 0.153920.15392, 0.41 - 2 \times 0.412 + 0.413 - 0.15392 + 0.41 \times 0.153920.15392)$ from which we drew a detection probability for each of the simulated AIR surveys during each iteration of the model.

Model Implementation

For each iteration of the model, we first determined which dens were exposed to each of the simulated activities and infrastructure. We assumed that any den within 1.6 km (1 mi) of infrastructure or human activities was exposed and had the potential to be disturbed as numerous studies have suggested a 1.6-km buffer is sufficient to reduce disturbance to denning polar bears (MacGillivray et al. 2003, Larson et al. 2020, Owen et al. 2021). If, however, a den was detected by an AIR survey prior to activity occurring within 1.6 km of it, we assumed a 1.6-km buffer would be established to restrict activity adjacent to the den and there would be no potential for future disturbance. If a den was detected by an AIR survey after activity occurred within 1.6 km of it, as long as the activity did not result in a Level A harassment or lethal take, we assumed a 1.6-km buffer would be applied to prevent disturbance during future denning periods. For dens exposed to human activity (*i.e.,* not detected by an AIR survey), we then identified the stage in the denning cycle when the exposure occurred based on the date range of the activities the den was exposed to. We then determined whether the exposure elicited a response by the denning bear based on probabilities derived from the reviewed case studies (table 5).

Level B harassment was applicable to both adults and cubs, if present, whereas Level A harassment (*i.e.,* serious injury and non-serious injury) and lethal take were applicable only to cubs because the specified activities had a discountable risk of running over dens and thus killing a female or impacting her future reproductive potential. The majority of the specified activities occur on established, permanent infrastructure or in areas that would not be suitable for denning and, therefore, pose no risk of being run over (*i.e.,* an existing road or pad). For those activities off permanent infrastructure (*i.e.,* ice roads and tundra travel routes), crews will constantly be on the lookout for signs of denning, use vehicle-based forward-looking infrared cameras to scan for dens, and will largely avoid crossing topographic features suitable for denning given operational constraints. Thus, the risk of running over a den was deemed to have a probability so low that it was discountable.

Based on JADE's description of their specified activities, we only considered AIR surveys as discrete exposures given that surveys occur quickly (*i.e.,* the time for an airplane to fly over) and infrequently. The case studies used to inform the post-emergence period include one where an individual fell into a den and caused the female to abandon her cubs. Therefore, we excluded this case study from the calculation of disturbance probabilities applied to our analysis, which led to a 0 percent probability of lethal take and a 100 percent probability of non-serious-injury Level A harassment.

If a Level A harassment or lethal take was simulated to occur, a den was not allowed to be disturbed again during the subsequent denning periods because the outcome of that denning event was already determined. As noted above, Level A harassments and lethal takes applied only to cubs because specified activities would not result in those levels of take for adult females. Adult females, however, could still receive Level B takes during the den establishment period or any time cubs received Level B harassment, Level A harassment (*i.e.,* serious injury and non-serious injury), or lethal take.

We developed the code to run this model in program R (R Core Development Team 2021) and ran 10,000 iterations of the model (*i.e.,* Monte Carlo simulation) to derive the estimated number of animals disturbed and associated levels of take.

Model Results

On average, we estimated 52 (median = 51; *95% CI:* 30–79) land-based dens along the North Slope of Alaska, within which JADE's proposal is located. Estimates for different levels of harassment takes are presented in table

6. We also estimated that Level B harassment from only AIR surveys was a mean of 0.49 (median = 0; 95% CI: 0–2). The distributions of both non-serious Level A harassment and serious Level A harassment/lethal takes were non-normal and heavily skewed, as indicated by markedly different mean and median values. The heavily skewed nature of these distributions has led to a mean value that is not representative of the most common model result (*i.e.,* the median value), which for both non-serious Level A and serious Level A harassment/lethal takes is 0.0. Due to the low (0.23 for non-serious Level A and 0.26 for serious Level A harassment takes) probability of greater than or equal to 1 non-serious or serious injury Level A harassment/lethal take each year of the proposed IHA period, combined with the median of 0.0 for each, we do not estimate the specified activities will result in non-serious-injury or serious-injury Level A harassment or lethal take of polar bears.

TABLE 6—RESULTS OF THE DEN DISTURBANCE MODEL FOR ALL PROPOSED ACTIVITIES DURING THE 1-YEAR IHA PERIOD. ESTIMATES ARE PROVIDED FOR THE PROBABILITY, MEAN, MEDIAN, AND 95% CONFIDENCE INTERVALS FOR LEVEL B, NON-SERIOUS LEVEL A, AND SERIOUS LEVEL A HARASSMENT/LETHAL TAKE. THE PROBABILITIES REPRESENT THE PROBABILITY OF ≥1 TAKE OF A BEAR OCCURRING DURING A GIVEN WINTER

Level B harassment	Probability	0.58
	Mean	1.40
	Median	1.0
	95% Confidence Interval	0–6
Non-Serious Level A	Probability	0.23
	Mean	0.51
	Median	0.0
	95% Confidence Interval	0–3
Serious Level A/Lethal	Probability	0.26
	Mean	0.58
	Median	0.0
	95% Confidence Interval	0–4

Evaluation of Impacts of Oil Spills on Polar Bears

To date, large oil spills from Industry activities in the Beaufort Sea and coastal regions that would impact polar bears have not occurred. Even small spills of oil or waste products have the potential to impact some bears. The effects of fouling fur or ingesting oil or wastes, depending on the amount of oil or wastes involved, could be short term or result in death. For example, in April 1988, a dead polar bear was found on Leavitt Island, northeast of Oliktok Point. The cause of death was determined to be ingestion of a mixture that included ethylene glycol and Rhodamine B dye (Amstrup et al. 1989). Again, in 2012, two dead polar bears that had ingested Rhodamine B were found on Narwhal Island, northwest of Endicott. While those bears' deaths were clearly human-caused, investigations were unable to identify a source for the chemicals. Rhodamine B is commonly used on the North Slope of Alaska by many people for many uses, including Industry. Without identified sources of contamination, those bear deaths are not attributed to Industry activity. Thus, we recognize potential impacts of even small spills of such materials. However, because specified activities are primarily occurring inland and during the ice season, thereby reducing the number of polar bears that may come in contact with any small spills that could occur and not be cleaned up at time of occurrence, impacts due to oil spills will be very unlikely.

Wilson *et al.* (2018) analyzed the potential effects of a ''worst case discharge'' (WCD) on polar bears in the Chukchi Sea. Their WCD scenario was based on an Industry oil spill response plan for offshore development in the region and represented underwater blowouts releasing 25,000 barrels of crude oil per day for 30 days beginning in October. The results of this analysis suggested that between 5 and 40 percent of a stock of 2,000 polar bears in the Chukchi Sea could be exposed to oil if a WCD occurred. A similar analysis has not been conducted for the Beaufort Sea; however, given the extremely low probability (*i.e.,* 0.0001) that an unmitigated WCD event would occur (BOEM 2016, Wilson *et al.* 2017), the likelihood of such effects on polar bears in the Beaufort Sea is extremely low.

Sum of Take From All Sources

The applicant proposes to conduct mobilization activities, well drilling, ice road and ice pad construction, and cleanup activities within the PBU and PTU of the North Slope of Alaska from December 1, 2021, to November 30, 2022. A summary of total estimated take via Level B harassment during the project by source is provided in table 7. The potential for lethal or Level A harassment was explored. Lethal take or Level A harassment would not occur outside of denning bears because the level of sound and visual stimuli on a bear on the surface would not be significant enough to result in injury or death. Denning bears, however, may be subject to repeated exposures, significant energy expenditure from den abandonment or departure, or potential impacts to a cub if the den is abandoned or departed prematurely. The probability of greater than or equal to 1 lethal or serious Level A take of denning polar bears was 0.25.

TABLE 7—TOTAL ESTIMATED LEVEL B HARASSMENT EVENTS OF POLAR BEARS AND SOURCE

Source	Estimated Level B harassment
Surface Interactions	0.21
Denning Impacts	1.40
Total	1.61

Critical Assumptions

In order to conduct this analysis and estimate the potential amount of Level B harassment, we made several critical assumptions.

Level B harassment is equated herein with behavioral responses that indicate harassment or disturbance. There is likely a portion of animals that respond in ways that indicate some level of disturbance but do not experience significant biological consequences. Our estimates do not account for variable responses by polar bear age and sex; however, sensitivity of denning bears was incorporated into the analysis. The available information suggests that polar bears are generally resilient to low

levels of disturbance. Females with dependent young and juvenile polar bears are physiologically the most sensitive (Andersen and Aars 2008) and most likely to experience harassment from disturbance. There is not enough information on composition of the SBS polar bear stock in the proposed project area to incorporate individual variability based on age and sex or to predict its influence on harassment estimates. Our estimates are derived from a variety of sample populations with various age and sex structures, and we assume the exposed population will have a similar composition and, therefore, the response rates are applicable.

The estimates of behavioral response presented here do not account for the individual movements of animals away from the project area or habituation of animals to noise or human presence. Our assessment assumes animals remain stationary (*i.e.,* density does not change). There is not enough information about the movement of polar bears in response to specific disturbances to refine this assumption.

Determinations and Findings

Small Numbers

For our small numbers determination, we consider whether the estimated number of polar bears to be subjected to incidental take is small relative to the population size of the species or stock.

1. We estimate JADE's proposed specified activities in the specified geographic region will take no more than 2 SBS polar bears by two Level B harassment during the 1-year period of this proposed IHA (see *Estimated Take: Sum of Take from All Sources*). Take of 2 animals is 0.2 percent of the best available estimate of the current SBS stock size of 907 animals SBS (Bromaghin et al. 2015, Atwood et al. 2020) ($(2 \div 907) \times 100 \approx 0.2$, and represents a ''small number'' of polar bears of that stock.

2. Within the specified geographical region, the area of proposed activity is expected to be small relative to the range of the SBS stock of polar bears. SBS polar bears range well beyond the boundaries of the proposed IHA region. As such, the IHA region itself represents only a subset of the potential area in which this species may occur. Further, only 17 percent of the IHA area (39,254 ha of 221,179 ha) is estimated to be impacted by the specified activities, even accounting for a disturbance zone surrounding industrial facility and transit routes. Thus, the Service concludes that the area of proposed activity will be relatively small compared to the range of the SBS stock of polar bears.

Conclusion

Therefore, we propose a finding that JADE's proposed specified activities will take by level B harassment only small numbers of the SBS polar bear stock because: (1) Only a small proportion of the polar bear stock will overlap with the areas where the specified activities will occur; and (2) only small numbers will be taken by harassment because the specified activities are limited in spatial and temporal extent reducing the number of SBS polar bears that could be encountered in the duration of the proposed IHA.

Negligible Impacts

For our negligible impacts determination, we considered the following:

1. The distribution and habitat use patterns of polar bears indicate that relatively few animals will occur in the specified areas of activity at any particular time and, therefore, few animals are likely to be affected.

2. The documented impacts of previous Industry activities on polar bears, taking into consideration cumulative effects, suggests that the types of activities analyzed for this proposed IHA will have minimal effects and will be short-term, temporary behavioral changes. The vast majority of reported polar bear observations have been of polar bears moving through the proposed IHA region, undisturbed by the Industry activity.

3. The relatively small area of the specified activities compared to the ranges of the SBS stock of polar bears will reduce the potential of their exposure to and disturbance from the specified activities.

4. The Service does not anticipate any lethal or injurious harassment take that would remove individual polar bears from the population or prevent their successful reproduction. Incidental harassment events are anticipated to be limited to human interactions that lead to short-term behavioral disturbances. These disturbances would not affect the rates of recruitment or survival for polar bear stocks. This proposed IHA does not authorize injurious or lethal take, and we do not anticipate any such take will occur.

5. If this IHA is finalized, the applicant will be required to adopt monitoring requirements and mitigation measures designed to reduce the potential impacts of their operations on polar bears. Den detection surveys for polar bears and adaptive mitigation and management responses based on real-time monitoring information (described in this proposed authorization) will be used to avoid or minimize interactions with polar bears and, therefore, limit potential disturbance of these animals.

We also considered the specific congressional direction in balancing the potential for a significant impact with the likelihood of that event occurring. The specific congressional direction that justifies balancing probabilities with impacts follows:

If potential effects of a specified activity are conjectural or speculative, a finding of negligible impact may be appropriate. A finding of negligible impact may also be appropriate if the probability of occurrence is low but the potential effects may be significant. In this case, the probability of occurrence of impacts must be balanced with the potential severity of harm to the species or stock when determining negligible impact. In applying this balancing test, the Service will thoroughly evaluate the risks involved and the potential impacts on marine mammal populations. Such determination will be made based on the best available scientific information (53 FR 8474, March 15, 1988; 132 Cong. Rec. S 16305 (October. 15, 1986)).

We reviewed the effects of the oil and gas exploration activities on polar bears, including impacts from surface interactions, aircraft overflights, and oil spills. Based on our review of these potential impacts, past Industry monitoring reports, and the biology and natural history of polar bear, we conclude that any incidental take reasonably likely to occur as a result of projected activities will be limited to short-term behavioral disturbances that would not affect the rates of recruitment or survival for the polar bear stock.

The probability of an oil spill that will cause significant impacts to polar bears appears extremely low due to the timing and location of specified activities. In the unlikely event of a catastrophic spill, we will take immediate action to minimize the impacts to this species and reconsider the appropriateness of authorizations for incidental taking through section 101(a)(5)(A) of the MMPA.

We have evaluated climate change regarding polar bears. Climate change is a global phenomenon and was considered as the overall driver of effects that could alter polar bear habitat and behavior. Though climate change is a pressing conservation issue for polar bears, we have concluded that the authorized incidental taking of polar bears during the activities proposed by JADE during this proposed 1-year authorization will not adversely impact

the survival of the species, or stock, and will have no more than negligible effects. The Service is currently involved in research to understand how climate change may affect polar bears. As we gain a better understanding of climate change effects, we will incorporate the information in future authorizations.

Therefore, we propose a finding that two Level B harassments in association with the specified activities addressed under this proposed IHA will have no more than a negligible impact on the SBS stock of polar bears. We do not expect any resulting disturbance to negatively impact the rates of recruitment or survival for the polar bear stock. This proposed IHA does not authorize lethal take, and we do not anticipate that any lethal take will occur.

Least Practicable Adverse Impact

We evaluated the practicability and effectiveness of mitigation measures based on the nature, scope, and timing of the specified activities; the best available scientific information; and monitoring data during Industry activities in the specified geographic region. We propose a finding that the mitigation measures included within JADE's Request will ensure least practicable adverse impacts on polar bears (JADE 2021).

Polar bear den surveys before activities begin during the denning season, the resulting 1.6-km (1-mi) operational exclusion zone around all known polar bear dens, and restrictions on the timing and types of activities in the vicinity of dens will ensure that impacts to denning female polar bears and their cubs are minimized during this critical time. Minimum flight elevations over polar bear areas and flight restrictions around known polar bear dens will reduce the potential for bears to be disturbed by aircraft. Finally, JADE will implement mitigation measures to prevent the presence and impact of attractants such as the use of wildlife-resistant waste receptacles and enclosing access doors and stairs. These measures are outlined in a polar bear interaction plan that was developed in coordination with the Service and is part of JADE's application for this IHA. Based on the information we currently have regarding den and aircraft disturbance and polar bear attractants, we concluded that the mitigation measures outlined in JADE's Request (JADE 2021) and incorporated into this authorization will minimize impacts from the specified oil and gas activities to the extent practicable.

A number of mitigation measures were considered but determined to be not practicable. These measures are listed below:

- *Required use of helicopters for AIR surveys*—Use of helicopters to survey active dens might lead to greater levels of disturbance and take compared to fixed-wing aircraft. Additionally, there is no published data to indicate increased den detection efficacy of helicopter AIR.
- *Grounding all flights if they must fly below 1,500 feet*—Requiring all aircraft to maintain an altitude of 1,500 ft at all times is not practicable as some operations may require flying below 1,500 ft to perform necessary inspections or maintain safety of flight crew. Aircraft are required, however, to fly above 1,500 ft at all times, except for emergencies, within 805 m (0.5 mi) of an observed polar bear.
- *Spatial and temporal restrictions on surface activity*—Some spatial and temporal restrictions of operations were included in JADE's Request; however, additional restrictions would not be practicable for the specified activities based on other regulatory and safety requirements.
- *One-mile buffer around all known polar bear denning habitat*—One-mile buffer around all known polar bear denning habitat is not practicable as most of the existing infrastructure used by JADE occurs within 1 mile of denning habitat, and they would not be able to shut down all operations based on other regulatory and safety requirements.
- *Prohibition of driving over high relief areas, embankments, or stream and river crossings*—While the denning habitat must be considered in tundra travel activities, complete prohibition is not practicable for safety reasons.
- *Use of a broader definition of ''denning habitat'' for operational offsets*—There is no available data to support broadening the defining features of denning habitat beyond that established by USGS. Such a redefinition would cause an increase in the area surveyed for maternal dens, and the associated increase in potential harassment of bears on the surface would outweigh the mitigative benefits.
- *Establishment of corridors for sow and cub transit to the sea ice*—As there is no data to support the existence of natural transit corridors to the sea ice, establishment of corridors in the IHA area would be highly speculative. Therefore, there would be no mitigative benefit realized by their establishment.
- *Requirement of third-party neutral marine mammal observers*—It is often not practicable to hire third-party marine mammal observers due to operational constraints. Additional crew may require additional transit vehicles, which could increase disturbance.
- *Require all activities to cease if a polar bear is injured or killed until an investigation is completed*—The Service has incorporated into this proposed authorization reporting requirements for all polar bear interactions. While it may aid in any subsequent investigation, ceasing all activities may not be practicable or safe in certain circumstances and, thus, will not be mandated.
- *Require use of den detection dogs*—It is not practicable or safe to require scent-trained dogs to detect dens due to the large spatial extent that would need to be surveyed along the winter trail route and project area.
- *Require the use of handheld or vehicle-mounted Forward Looking Infrared (FLIR)*—The efficacy rates for AIR have been found to be four times more likely to detect dens versus ground-based FLIR (handheld or vehicle-mounted FLIR) due to impacts of blowing snow on detection. There would likely be no additional benefit to requiring ground-based FLIR methods.

Impact on Subsistence Use

Based on past community consultations, locations of hunting areas, no anticipated overlap of hunting areas and Industry projects, and the best scientific information available, including monitoring data from similar activities, we propose a finding that take caused by the proposed oil and gas exploration activities in the project area will not have an unmitigable adverse impact on the availability of polar bears for taking for subsistence uses during the proposed timeframe.

While polar bears represent a small portion, in terms of the number of animals, of the total subsistence harvest for the Kaktovik community, the harvest of these species is important to Alaska Natives. JADE will be required to contact subsistence communities that may be affected by its activities to discuss potential conflicts caused by location, timing, and methods of proposed operations. JADE must make reasonable efforts to ensure that activities do not interfere with subsistence hunting and that adverse effects on the availability of polar bears are minimized. Although past meetings for the proposed project, prior to being postponed due to the coronavirus pandemic, have already taken place, no official concerns have been voiced by the Alaska Native communities regarding project activities limiting availability of polar bears for

subsistence uses. However, should such a concern be voiced, development of Plans of Cooperation (POCs), which must identify measures to minimize any adverse effects, will be required. The POC will ensure that project activities will not have an unmitigable adverse impact on the availability of the species or stock for subsistence uses. This POC must provide the procedures addressing how JADE will work with the affected Alaska Native communities and what actions will be taken to avoid interference with subsistence hunting of polar bears, as warranted.

The Service has not received any reports and is not aware of information that indicates that polar bears are being or will be deterred from hunting areas or impacted in any way that diminishes their availability for subsistence use by the expected level of oil and gas activity. If there is evidence that these oil and gas activities are affecting the availability of polar bears for take for subsistence uses, we will reevaluate our findings regarding permissible limits of take and the measures required to ensure continued subsistence hunting opportunities.

Monitoring and Reporting

The purpose of monitoring requirements is to assess the effects of project activities on polar bears, ensure that take is consistent with that anticipated in the negligible impact and subsistence use analyses, and detect any unanticipated effects on the species or stock. Monitoring plans document when and how bears are encountered, the number of bears, and their behavior during the encounter. This information allows the Service to measure encounter rates and trends of polar bear activity in the industrial areas (such as numbers and gender, activity, seasonal use) and to estimate numbers of animals potentially affected by Industry. Monitoring plans are site-specific, dependent on the proximity of the activity to important habitat areas, such as den sites, travel corridors, and food sources; however, JADE is required to report all sightings of polar bears. To the extent possible, monitors will record group size, age, sex, reaction, duration of interaction, and closest approach to facilities onshore. Activities within the specified geographic region may incorporate daily watch logs as well, which record 24-hour animal observations throughout the duration of the project. Polar bear monitors will be incorporated into the monitoring plan if bears are known to frequent the area or known polar bear dens are present in the area.

The Service will provide JADE with the most recent and up-to-date Polar Bear Observation Form in which to record sightings of bears. Sightings must be reported to the Service Office of Marine Mammal Management (MMM) within 48 hours of the sighting and submitted to *fw7_mmm_reports@fws.gov.* Details on monitoring guidelines and reporting requirements can be read below in Proposed Authorization, (C) Monitoring and (E) Reporting Requirements.

Required Determinations

National Environmental Policy Act (NEPA)

We have prepared a draft environmental assessment in accordance with the NEPA (42 U.S.C. 4321 *et seq.).* We have preliminarily concluded that authorizing the nonlethal, incidental take by Level B harassment of up to two polar bears from the SBS stock in the specified geographic region during the specified activities during the regulatory period would not significantly affect the quality of the human environment and, thus, preparation of an environmental impact statement for this incidental harassment authorization is not required by section 102(2) of NEPA or its implementing regulations. We are accepting comments on the draft environmental assessment as specified above in **DATES** and **ADDRESSES**.

Endangered Species Act

Under the ESA (16 U.S.C. 1536(a)(2)), all Federal agencies are required to ensure the actions they authorize are not likely to jeopardize the continued existence of any threatened or endangered species or result in destruction or adverse modification of critical habitat. Prior to issuance of this proposed IHA, the Service will complete intra-Service consultation under section 7 of the ESA on our proposed issuance of an IHA. These evaluations and findings will be made available on the Service's website at *https://ecos.fws.gov/ecp/report/biological-opinion.* The authorization of incidental take of polar bears and the measures included in the proposed IHA will not affect other listed species or designated critical habitat.

Government-to-Government Coordination

It is our responsibility to communicate and work directly on a Government-to-Government basis with federally recognized Alaska Native Tribes and Alaska Native Claims Settlement Act (ANCSA) corporations in developing programs for healthy ecosystems. We seek their full and meaningful participation in evaluating and addressing conservation concerns for protected species. It is our goal to remain sensitive to Alaska Native culture, and to make information available to Alaska Natives. Our efforts are guided by the following policies and directives: (1) *The Native American Policy of the Service* (January 20, 2016); (2) *The Alaska Native Relations Policy* (currently in draft form); (3) *Executive Order 13175* (January 9, 2000); (4) *Department of the Interior Secretarial Orders 3206* (June 5, 1997), *3225* (January 19, 2001), *3317* (December 1, 2011), and *3342* (October 21, 2016); (5) *The Alaska Government-to-Government Policy* (a departmental memorandum issued January 18, 2001); and (6) the Department of the Interior's policies on consultation with Alaska Native Tribes and organizations.

We have evaluated possible effects of the specified activities on federally recognized Alaska Native Tribes and organizations. Through the IHA process identified in the MMPA, the applicant has presented a communication process, culminating in a POC if needed, with the Native organizations and communities most likely to be affected by their work. The Service does not anticipate impacts to Alaska Native Tribes or ANCSA corporations and does not anticipate requesting consultation; however, we invite continued discussion, either about the project and its impacts or about our coordination and information exchange throughout the IHA/POC process.

Proposed Authorization

We propose to authorize the nonlethal, incidental take by Level B harassment of two SBS stock polar bears. Authorized take will be limited to disruption of behavioral patterns that may be caused by oil and gas exploration and support activities conducted by JADE Energy Inc. (JADE) in the Prudhoe Bay Unit (PBU) and the Point Thomson Unit (PTU) of the North Slope of Alaska, from December 1, 2021, through November 30, 2022. We do not anticipate or authorize any take by Level A harassment, injury, or death to polar bears resulting from these activities.

A. General Conditions for This IHA

(1) Activities must be conducted in the manner described in the request dated August 2, 2021, for an IHA and in accordance with all applicable conditions and mitigation measures. The taking of polar bears whenever the required conditions, mitigation, monitoring, and reporting measures are

not fully implemented as required by the IHA is prohibited. Failure to follow the measures specified both in the revised request and within this proposed authorization may result in the modification, suspension, or revocation of the IHA.

(2) If project activities cause unauthorized take (*i.e.,* take of more than two polar bears, a form of take other than Level B harassment, or take of one or more polar bears through methods not described in the IHA), JADE must take the following actions: (i) Cease its activities immediately (or reduce activities to the minimum level necessary to maintain safety); (ii) report the details of the incident to the Service within 48 hours; and (iii) suspend further activities until the Service has reviewed the circumstances and determined whether additional mitigation measures are necessary to avoid further unauthorized taking.

(3) All operations managers, vehicle operators, and aircraft pilots must receive a copy of this IHA and maintain access to it for reference at all times during project work. These personnel must understand, be fully aware of, and be capable of implementing the conditions of the IHA at all times during project work.

(4) This IHA will apply to activities associated with the proposed project as described in this document and in JADE's revised request. Changes to the proposed project without prior authorization may invalidate the IHA.

(5) JADE's request is approved and fully incorporated into this IHA, unless exceptions are specifically noted herein. The request includes:

- JADE's original request for an IHA, dated May 19, 2021 (JADE 2021);
- The letters requesting additional information, dated May 25, 2021;
- JADE's responses to requests for additional information from the Service, dated May 25, 2021;
- JADE's revised request for an IHA, dated June 9, 2021;
- JADE's revised request for an IHA, dated August 2, 2021; and
- The *JADE Exploration and Appraisal Program Wildlife Avoidance and Interaction Plan* (Appendix A in JADE 2021).

(6) Operators will allow Service personnel or the Service's designated representative to visit project work sites to monitor for impacts to polar bears and subsistence uses of polar bears at any time throughout project activities so long as it is safe to do so. ''Operators'' are all personnel operating under JADE's authority, including all contractors and subcontractors.

B. Avoidance and Minimization

JADE must implement the following policies and procedures to avoid interactions with and minimize to the greatest extent practicable any adverse impacts on polar bears, their habitat, and the availability of these marine mammals for subsistence uses.

(a) *General avoidance measures.*

(1) JADE must cooperate with the Service and other designated Federal, State, and local agencies to monitor and mitigate the impacts of activities on polar bears.

(2) Trained and qualified personnel must be designated to monitor at all times for the presence of polar bears, initiate mitigation measures, and monitor, record, and report the effects of the activities on polar bears. JADE must provide all operators with polar bear awareness training prior to their participation in project activities. Delivery of this polar bear awareness training must include Service participation.

(3) A Service-approved polar bear safety, awareness, and interaction plan must be on file with the Service Marine Mammal Management office and available onsite. The interaction plan must include:

(i) A description of the proposed activity (*i.e.,* a summary of the plan of operations during the proposed activity);

(ii) A food, waste, and other attractants management plan;

(iii) Personnel training policies, procedures, and materials;

(iv) Site-specific polar bear interaction risk evaluation and mitigation measures;

(v) Polar bear avoidance and encounter procedures; and

(vi) Polar bear observation and reporting procedures.

(4) JADE must contact potentially affected subsistence communities and hunter organizations to discuss potential conflicts caused by the activities and provide the Service documentation of communications as described in (D) *Measures To Reduce Impacts to Subsistence Users.*

(b) *Mitigation measures for onshore activities.* JADE must undertake the following activities to limit disturbance around known polar bear dens:

(1) *Attempt to locate bear dens.* JADE must conduct two surveys for occupied polar bear dens in all denning habitat within 1.6 km (1 mi) of specified activities using AIR imagery. The first survey must occur prior to construction activities between the dates of November 25 and December 15, and a second survey must be performed between the dates of December 5 and December 31. All observed or suspected polar bear dens must be reported to the Service prior to the initiation of activities.

(i) AIR surveys will be conducted during darkness or civil twilight and not during daylight hours. Ideal environmental conditions during surveys would be clear, calm, and cold. If there is blowing snow, any form of precipitation, or other sources of airborne moisture, use of AIR detection is not advised. Flight crews will record and report environmental parameters including air temperature, dew point, wind speed and direction, cloud ceiling, and percent humidity, and a flight log will be provided to the Service within 48 hours of the flight.

(ii) A scientist experienced in interpreting AIR imagery will be on board the survey aircraft to analyze the AIR data in real-time. The data (infrared video) will be available for viewing by the Service immediately upon return of the survey aircraft to the base of operations in Deadhorse, Alaska. Data will be transmitted electronically to the Service in Anchorage for review.

(iii) If a suspected den site is located, JADE will immediately consult with the Service to analyze the data and determine if additional surveys or mitigation measures are required. All located dens will be subject to the 1.6-km (1.0-mi) exclusion zone as described in paragraph (b)(1) of this section. The Service will determine whether the suspected den is to be treated as a putative den for the purposes of this IHA.

(2) *Observe 1-mile operational exclusion zone around known polar bear dens.* Operators must observe a 1.6-km (1-mi) operational exclusion zone around all putative polar bear dens during the denning season (November–April, or until the female and cubs leave the areas). Should previously unknown occupied dens be discovered within 1 mile of activities, work must cease, and the Service contacted for guidance. The Service will evaluate these instances on a case-by-case basis to determine the appropriate action. Potential actions may range from cessation or modification of work to conducting additional monitoring, and the holder of the authorization must comply with any additional measures specified.

(3) *Use the den habitat map developed by the USGS.* In determining the denning habitat that requires surveys, use the den habitat map developed by the USGS. A map of potential coastal polar bear denning habitat can be found at: *https://www.usgs.gov/centers/asc/science/polar-bear-maternal-denning?qt-*

science_center_objects=4#qt-science_center_objects.

(4) *Temporal restriction after July 18.* Proposed cleanup activities must conclude prior to July 19 to reduce the likelihood of disturbance to polar bears and potential for human-polar bear interactions.

(c) *Mitigation measures for aircraft.*

(1) *Aircraft elevation and flight path restrictions to avoid disturbance.* Operators of support aircraft should, at all times, conduct their activities at the maximum distance practicable from concentrations of polar bears. Under no circumstances, other than an emergency, will aircraft operate at an altitude lower than 457 m (1,500 ft) within 805 m (0.5 mi) of polar bears observed on ice or land measured in a straight line between the bear and the ground directly underneath the plane. Aircraft may be operated below 457 m (1,500 ft) only when necessary to avoid adverse weather conditions. However, when weather conditions necessitate operation of aircraft at altitudes below 457 m (1,500 ft), the operator must avoid areas of known polar bear concentrations and should take precautions to avoid flying directly over or within 805 m (0.5 mile) of these areas.

(2) *Aircraft landing and take-off spatial restrictions.* Aircraft will not land within 805 m (0.5 mi) of a polar bear. If a polar bear is observed while the aircraft is grounded, personnel will board the aircraft and leave the area. The pilot will also avoid flying over the polar bear if possible. Pilots should avoid making any sudden maneuvers, especially when traveling at lower altitudes, even if such maneuvers are intended to avoid polar bears. The Service recommends that if a polar bear is spotted within the landing zone or work area, aircraft operators travel away from the site, and slowly increase altitude to 1,500 ft or a level that is safest and viable given current traveling conditions. Aircraft may not be operated in such a way as to separate individual polar bears from a group of polar bears.

C. Monitoring

(1) Operators must provide onsite observers and implement the Service-approved polar bear avoidance and interaction plan to apply mitigation measures, monitor the project's effects on polar bears and subsistence uses, and to evaluate the effectiveness of mitigation measures.

(2) All onsite observers shall complete a Service-provided training course designed to familiarize individuals with monitoring and mitigation activities identified in the polar bear avoidance and interaction plan.

(3) Onsite observers must be present during all operations and must record all polar bear observations, identify and document potential harassment, and work with personnel to implement appropriate mitigation measures.

(4) Operators shall cooperate with the Service and other designated Federal, State, and local agencies to monitor the impacts of project activities on polar bears. Where information is insufficient to evaluate the potential effects of activities on polar bears and the subsistence use of this species, JADE may be required to participate in joint monitoring efforts to address these information needs and ensure the least practicable impact to this resource.

(5) Operators must allow Service personnel or the Service's designated representative to visit project work sites to monitor impacts to polar bear and subsistence use at any time throughout project activities so long as it is safe to do so.

D. Measures To Reduce Impacts to Subsistence Users

JADE must conduct its activities in a manner that, to the greatest extent practicable, minimizes adverse impacts on the availability of polar bears for subsistence uses.

(1) JADE will be required to develop a Service-approved Plan of Cooperation (POC) if, through community consultation, concerns are raised regarding impacts to subsistence harvest or Alaska Native Tribes and organizations.

(2) If required, JADE will implement the Service-approved POC.

(3) Prior to conducting the work, JADE will take the following steps to reduce potential effects on subsistence harvest of polar bears: (i) Avoid work in areas of known polar bear subsistence harvest; (ii) discuss the planned activities with subsistence stakeholders including the North Slope Borough, the Native Village of Kaktovik, the State of Alaska, the Service, the Bureau of Land Management, and other interested parties on a Federal, State, and local regulatory level; (iii) identify and work to resolve concerns of stakeholders regarding the project's effects on subsistence hunting of polar bears; (iv) if any unresolved or ongoing concerns remain, modify the POC in consultation with the Service and subsistence stakeholders to address these concerns; and (v) develop mitigation measures that will reduce impacts to subsistence users and their resources.

E. Reporting Requirements

JADE must report the results of monitoring to the Service MMM via email at: *fw7_mmm_reports@fws.gov.*

(1) *In-season monitoring reports.*

(i) *Activity progress reports.* JADE must:

(A) Notify the Service at least 48 hours prior to the onset of activities;

(B) Provide the Service weekly progress reports summarizing activities. Reports must include GPS/GIS tracks of all vehicles including scout vehicles in *.kml* or *.shp* format with time/date stamps and metadata.

(C) Notify the Service within 48 hours of project completion or end of the work season.

(ii) *Polar bear observation reports.* JADE must report, within 48 hours, all observations of polar bears and potential polar bear dens during any project activities including AIR surveys. Upon request, monitoring report data must be provided in a common electronic format (to be specified by the Service). Information in the observation report must include, but need not be limited to:

(A) Date and time of each observation;

(B) Locations of the observer and bears (GPS coordinates if possible);

(C) Number of polar bears;

(D) Sex and age class—adult, subadult, cub (if known);

(E) Observer name and contact information;

(F) Weather, visibility, and if at sea, sea state, and sea-ice conditions at the time of observation;

(G) Estimated closest distance of polar bears from personnel and facilities;

(H) Type of work being conducted at time of sighting;

(I) Possible attractants present;

(J) Polar bear behavior—initial behavior when first observed (*e.g.,* walking, swimming, resting, etc.);

(K) Potential reaction—behavior of bear potentially in response to presence or activity of personnel and equipment;

(L) Description of the encounter;

(M) Duration of the encounter; and

(N) Mitigation actions taken.

(2) *Notification of human-bear interaction incident report.* JADE must report all human-bear interaction incidents immediately, and not later than 48 hours after the incident. A human-bear interaction incident is any situation in which there is a possibility for unauthorized take. For instance, when project activities exceed those included in an IHA, when a mitigation measure was required but not enacted, or when injury or death of a polar bear occurs. Reports must include:

(i) All information specified for an observation report in paragraphs (1)(ii)(A)–(N) of this section E;

(ii) A complete detailed description of the incident; and

(iii) Any other actions taken.

Injured, dead, or distressed polar bears that are clearly not associated with project activities (*e.g.,* animals found outside the project area, previously wounded animals, or carcasses with moderate to advanced decomposition or scavenger damage) must also be reported to the Service immediately, and not later than 48 hours after discovery. Photographs, video, location information, or any other available documentation must be included.

(3) *Final report.* The results of monitoring and mitigation efforts identified in the polar bear avoidance and interaction plan must be submitted to the Service for review within 90 days of the expiration of this IHA. Upon request, final report data must be provided in a common electronic format (to be specified by the Service). Information in the final report must include, but need not be limited to:

(i) Copies of all observation reports submitted under the IHA;

(ii) A summary of the observation reports;

(iii) A summary of monitoring and mitigation efforts including areas, total hours, total distances, and distribution;

(iv) Analysis of factors affecting the visibility and detectability of polar bears during monitoring;

(v) Analysis of the effectiveness of mitigation measures;

(vi) A summary and analysis of the distribution, abundance, and behavior of all polar bears observed; and

(vii) Estimates of take in relation to the specified activities.

Request for Public Comments

If you wish to comment on this proposed authorization, the associated draft environmental assessment, or both documents, you may submit your comments by either of the methods described in **ADDRESSES**. Please identify if you are commenting on the proposed authorization, draft environmental assessment, or both, make your comments as specific as possible, confine them to issues pertinent to the proposed authorization, and explain the reason for any changes you recommend. Where possible, your comments should reference the specific section or paragraph that you are addressing. The Service will consider all comments that are received before the close of the comment period (see **DATES**). The Service does not anticipate extending the public comment period beyond the 30 days required under section 101(a)(5)(D)(iii) of the MMPA.

Comments, including names and street addresses of respondents, will become part of the administrative record for this proposal. Before including your address, telephone number, email address, or other personal identifying information in your comment, be advised that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comments to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so.

Karen Cogswell,

Acting Regional Director, Alaska Region.

[FR Doc. 2021–24371 Filed 11–3–21; 4:15 pm]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R4–ES–2021–0124; FXES11130400000EA–123–FF04EF4000]

Receipt of Incidental Take Permit Application and Proposed Habitat Conservation Plan for the Eastern Indigo Snake, Citrus County, FL; Categorical Exclusion

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment and information.

SUMMARY: We, the Fish and Wildlife Service (Service), announce receipt of an application from Florida Department of Transportation—Florida's Turnpike Enterprise (applicant) (Suncoast Parkway 2) for an incidental take permit (ITP) under the Endangered Species Act. The applicant requests the ITP to take the federally listed eastern indigo snake incidental to construction of the four-lane Suncoast Parkway 2 in Citrus County, Florida. We request public comment on the application, which includes the applicant's proposed habitat conservation plan (HCP), and the Service's preliminary determination that this HCP qualifies as ''low-effect,'' categorically excluded, under the National Environmental Policy Act. To make this determination, we used our environmental action statement and low-effect screening form, both of which are also available for public review.

DATES: We must receive your written comments on or before *December 6, 2021.*

ADDRESSES:

Obtaining Documents: You may obtain copies of the documents online in Docket No. FWS–R4–ES–2021–0124 at *http://www.regulations.gov.*

Submitting Comments: If you wish to submit comments on any of the documents, you may do so in writing by any of the following methods:

- *Online: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R4–ES–2021–0124.
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–R4–ES–2021–0124; U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Zakia Williams, by telephone at 904–731–3119 or via email at *zakia_williams@fws.gov.* Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the Fish and Wildlife Service (Service), announce receipt of an application from Florida Department of Transportation—Florida's Turnpike Enterprise (applicant) for an incidental take permit (ITP) under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The applicant requests the ITP to take the federally listed eastern indigo snake (*Drymarchon corais couperii*) incidental to the construction of the four-lane Suncoast Parkway 2 (project) in Citrus County, Florida. We request public comment on the application, which includes the applicant's proposed habitat conservation plan (HCP), and the Service's preliminary determination that this HCP qualifies as ''low-effect,'' categorically excluded, under the National Environmental Policy Act (NEPA; 42 U.S.C. 4231 *et seq.*). To make this determination, we used our environmental action statement and low-effect screening form, which are also available for public review.

Project

Florida Department of Transportation—Florida's Turnpike Enterprise requests a 10-year ITP to take no more than two eastern indigo snakes (one male and one female) and one eastern indigo snake egg clutch incidental to the construction of the Suncoast Parkway 2. The take is based on the estimated home range of the species and the conversion of approximately 140 acres (ac) of occupied eastern indigo snake foraging and sheltering habitat during construction of the roadway from SR 44 to CR 486 in Sections 29, 30, 32, Township 18S, Range 18E, Citrus County, Florida. The applicant proposes

to mitigate for take of the eastern indigo snake by implementing conservation measures in the Standard Protection Measures for the Eastern Indigo Snake (Service 2013), which primarily focus on the preservation of the species during land conversion. The applicant will also install and maintain silt fence and chain-link fence along the entire project boundary and the perimeter of the project area to deter the species from entering the roadway and to reduce wildlife interactions within the construction zone. In addition to these measures, the applicant will contribute $22,820, which is calculated as $163 per ac of converted habitat, to the Wildlife Foundation of Florida—Eastern Indigo Snake Conservation Fund. This contribution will be used to help ensure the long-term viability of the species by maintaining and enhancing existing populations via habitat conservation, restoration, and management; monitoring the status of the extant populations; identifying and securing additional eastern indigo snake populations and habitat; repatriating populations through reintroductions; and supporting research that guides land management and provides demographic and ecological data. The Service would require the applicant to make the contribution to the Fund prior to engaging in activities associated with the project.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, be aware that your entire comment, including your personal identifying information, may be made available to the public. While you may request that we withhold your personal identifying information, we cannot guarantee that we will be able to do so.

Our Preliminary Determination

The Service has made a preliminary determination that the applicant's project, including land clearing, infrastructure building, landscaping, and the proposed mitigation measures, would individually and cumulatively have a minor or negligible effect on the eastern indigo snake and the environment. Therefore, we have preliminarily concluded that the ITP for this project would qualify for categorical exclusion and the HCP is low effect under our NEPA regulations at 43 CFR 46.205 and 46.210. A low-effect HCP is one that would result in (1) minor or negligible effects on federally listed, proposed, and candidate species and their habitats; (2) minor or negligible effects on other environmental values or resources; and (3) impacts that, when considered together with the impacts of other past, present, and reasonably foreseeable similarly situated projects, would not over time result in significant cumulative effects to environmental values or resources.

Next Steps

The Service will evaluate the application and the comments received to determine whether to issue the requested permit. We will also conduct an intra-Service consultation pursuant to section 7 of the ESA to evaluate the effects of the proposed take. After considering the preceding findings, we will determine whether the permit issuance criteria of section 10(a)(1)(B) of the ESA have been met. If met, the Service will issue ITP number PER0017213 to Florida Department of Transportation—Florida's Turnpike Enterprise.

Authority

The Service provides this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.32) and NEPA (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6 and 43 CFR 46.305).

Robert L. Carey,

Division Manager, Environmental Review, Florida Ecological Services Field Office.

[FR Doc. 2021–24126 Filed 11–4–21; 8:45 am]

BILLING CODE 4333–15–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Integrated Circuits, Chipsets, and Electronic Devices, and Products Containing the Same, DN 3574;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of NXP Semiconductors N.V. and NXP USA, Inc., on November 1, 2021. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain integrated circuits, chipsets, and electronic devices, and products containing the same. The complainant names as respondents: MediaTek Inc. of China; MediaTek USA Inc. of San Jose, CA; Amazon.com, Inc. of Seattle, WA; Belkin International, Inc. of Playa Vista, CA; and Linskys USA, Inc. of Irvine, CA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3574'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*.) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: November 1, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–24173 Filed 11–4–21; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 20–29]

George Roussis, M.D.; Decision and Order

On August 10, 2020, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to George Roussis, M.D. (hereinafter, Respondent), of Staten Island, New York. Order to Show Cause (hereinafter, OSC), at 1 and 3. The OSC proposed the denial of Respondent's application for DEA Certificate of Registration, Control No. W20041078C, because Respondent was excluded from ''participation in Medicare, Medicaid, and all Federal health care programs pursuant to section 1320a–7(a) of Title 42'' and such exclusion ''warrants denial of [Respondent's] application for a DEA registration pursuant to 21 U.S.C. 824(a)(5).'' *Id.* at 1–2 (citing *Narciso A. Reyes, M.D.,* 83 FR 61,678 (2018)).

Specifically, the OSC alleged that, on or about October 16, 2017, a judgment was entered against Respondent based on his conviction on one count of ''Racketeering-Transporting In Aid of Travel Act-Acceptance of Bribes'' in violation of 18 U.S.C. 1952(a)(3) and 2. *Id.* at 1 (citing *U.S.* v. *George Roussis,* No. 2:17–CR–00232–SRC–1 (D.N.J. Oct. 16, 2017)). The OSC further alleged that ''[b]ased on [Respondent's] conviction, the U.S. Department of Health and Human Services, Office of [the] Inspector General (''HHS/OIG''), mandatorily excluded [Respondent] from participation in Medicare, Medicaid, and all Federal health care programs pursuant to 42 U.S.C. § 1320a–7(a).'' *Id.* at 2. According to the OSC, the exclusion was effective on April 19, 2018, and runs for 13 years. *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). The OSC also notified Respondent of the opportunity to submit a corrective action plan. *Id.* at 2–3 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated September 2, 2020, Respondent timely requested a hearing. Administrative Law Judge Exhibit (hereinafter, ALJX) 2. The matter was placed on the docket of the Office of Administrative Law Judges and was assigned to Administrative Law Judge John J. Mulrooney, II (hereinafter, the Chief ALJ). On September 11, 2020, the Chief ALJ issued an Order for Prehearing Statements. ALJX 3. The Government timely filed its prehearing statement on September 25, 2020. ALJX 4. Respondent timely filed his prehearing statement on October 1, 2020. ALJX 5. On October 19, 2020, the Chief ALJ issued a prehearing ruling that, among other things, established the schedules and procedures for the remaining prehearing activities and for the hearing. ALJX 6 (Prehearing Ruling, at 1–7).

The hearing in this matter took place via video teleconference on December 16, 2020. Following the hearing, both the Government and Respondent filed their post-hearing briefs on January 22, 2021. On January 26, 2021, the Chief ALJ issued the Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (hereinafter, RD). Neither party filed exceptions to the RD. *See generally* Transmittal Letter. I have reviewed and agree with the procedural rulings of the Chief ALJ during the administration of the hearing.

Having considered the record in its entirety, I agree with the Chief ALJ and find that the record established by substantial evidence a *prima facie* case supporting the denial of Respondent's application. RD, at 12. I also agree with the Chief ALJ that Respondent failed to fully accept responsibility for his misconduct, failed to demonstrate that the Agency can entrust him to maintain his registration, and that denial of his application is appropriate. *Id.* at 12–15. I make the following findings of fact.

I. Findings of Fact

A. Respondent's Application for DEA Registration

Agency records show that on April 30, 2020, Respondent applied for DEA registration No. W20041078C as a practitioner authorized to handle controlled substances in Schedules II–V at the proposed registered location of 4735 Hylan Blvd., Staten Island, New York 10312. GX 1, at 1; *see also* RD, at 3 (Stipulation 1). Respondent previously held DEA registration No. BR7710999. GX 2, at 2. Respondent's previous DEA registration was the subject of an OSC issued on February 19, 2019, based on the sole allegation that Respondent was without authority to handle controlled substances in New York, the state in which he was registered with the DEA, because his New York medical license had been suspended. *Id.* at 1–2. The OSC was dismissed when the suspension of Respondent's New York medical license was lifted subject to probation and other conditions on August 16, 2019. *Id.* at 2. The expiration date of Respondent's previous DEA registration was April 30, 2020, and it is in retired status. *Id.*

B. Respondent's Criminal Conviction

The evidence in the record demonstrates that on June 21, 2017, an Information was filed in the United States District Court for the District of New Jersey against Respondent. GX 3. The Information charged that from October 2010 through April 2013, Respondent engaged in commercial bribery in violation of N.J.S.A. § 2C:21–10, 18 U.S.C. 1952(a)(3). *Id.* at 4. The Information charged that from October 2010 through April 2013, Biodiagnostic Laboratory Services, LLC (hereinafter, BLS), a clinical blood laboratory, paid Respondent and his brother bribes of approximately $175,000 in the aggregate to refer patient blood specimens to BLS. *Id.* at 1 and 4. The Information charged that BLS used the patient blood specimens from Respondent to submit claims to Medicare and private insurers to collect approximately $1,450,000. *Id.* at 4. Further, the Information charged that between October 2010 and April 2013, ''in addition to cash payments'' and ''at the request of [Respondent], on multiple occasions,'' BLS paid bribes to Respondent and his brother in the form of trips to strip clubs where ''BLS paid for women to perform lap dances on, and engage in sex acts with, [Respondent] and [Respondent's brother], in order to induce [Respondent] to refer the blood specimens of [Respondent's] patients to BLS for testing and related services.'' *Id.* On June 21, 2017, Respondent pled guilty to the charge of Racketeering-Transporting in Aid of Travel Act-Acceptance of Bribes in violation of 18 U.S.C. 1952(a)(3) & 18 U.S.C. 2. GX 5, at 1. Judgment was entered on October 16, 2017, and as a result of his guilty plea, Respondent was sentenced to serve 37 months in prison, pay a fine of $7,500, and forfeit $175,000 ''jointly and severally with [his brother].'' GX 3, at 6; GX 4, at 4; GX 5, at 1–2, 7, and 8; *see also* RD, at 3 (Stipulation 2).

C. Respondent's Exclusion

Based on Respondent's guilty plea and conviction, on March 30, 2018, HHS/OIG excluded Respondent from participation in Medicare, Medicaid, and all federal health care programs for a minimum period of 13 years pursuant to 42 U.S.C § 1320a–7(a). GX 7, at 1; *see also* RD, at 3 (Stipulation 4).

D. Respondent's State Medical License

Respondent was authorized to practice medicine in the State of New York by issuance of license number 224106. GX 2, at 2. Following Respondent's guilty plea and conviction, Respondent's New York medical license was suspended for 15 months starting from May 16, 2018. *Id.* On August 16, 2019, Respondent's state medical license was reinstated subject to probation for five years. *Id.* According to the State of New York's online records, the status of Respondent's state medical license is currently listed as ''Registered.'' *http://www.op.nysed.gov/opsearches.htm* (last visited date of signature of this Order). Following his conviction, Respondent was also excluded from participation in the New York State Medicaid program, effective November 5, 2017. GX 6, at 1–2.

E. The Parties' Positions

1. Government's Position

The OSC's sole allegation is that Respondent's exclusion from federal health care programs pursuant to 42 U.S.C. 1320a–7(a) warrants denying his application under 21 U.S.C. 824(a)(5). OSC, at 2. The Government alleges that Respondent's exclusion was based on his conviction on one count of Racketeering-Transporting In Aid of Travel Act-Acceptance of Bribes, in violation of 18 U.S.C. 1952(a)(3) & 18 U.S.C. 2. *Id.* at 1–2.

The Government's documentary evidence includes a copy of Respondent's application for DEA registration No. W20041078C as well as a copy of the Certification of Non Registration for DEA registration No. W20041078C. *See* GX 1 and 2. The Government's documentary evidence also includes a copy of the Information filed in the United States District Court for the District of New Jersey against Respondent as well as Respondent's Plea Agreement and the Judgment following Respondent's conviction. *See* GX 3–5. Additionally, the Government's documentary evidence includes a copy of Respondent's exclusion letter from HHS/OIG as well as a website screen print from the HHS/OIG exclusions database showing that Respondent is excluded. *See* GX 7 and 8. Finally, the Government's documentary evidence includes a copy of Respondent's exclusion letter from the New York State Medicaid program. *See* GX 6.

The Government called one witness to testify at the hearing, a Group Supervisor (GS) who works for the DEA New York Field Division. The GS testified about her career experience, including her previous encounter with Respondent when Respondent's prior DEA registration was the subject of an OSC because Respondent's New York medical license had been suspended. Tr. 15–21; *see also* RD, at 3; GX 2, at 1–2. The GS also authenticated the Government's documentary evidence and testified about her investigation-related actions, including obtaining the Government's documentary evidence and confirming that Respondent's exclusion from federal health care programs was still in effect. Tr. 15–37; *see also* RD, at 3–4.

Having read and analyzed all of the record evidence, I agree with the Chief ALJ that the testimony from the GS was

''sufficiently detailed, plausible, and internally consistent,'' and that the GS ''presented as an objective regulator and investigator with no discernable motive to fabricate or exaggerate.'' RD, at 4.

2. Respondent's Position

Respondent requested a hearing in response to the Government's OSC, asserting that although his medical license had been restored, without a DEA registration, he was not able to effectively practice. Request for a Hearing (hereinafter, Hearing Request).

The Respondent's documentary evidence includes various orders from the New York State Department of Health regarding the status of Respondent's medical license following his conviction. *See* RX 1–3. The Respondent's documentary evidence also includes a collection of support letters from patients, colleagues, and friends that had been previously submitted to the District of New Jersey as part of Respondent's criminal case. *See* RX 4. Respondent was the sole witness to testify for his case.

Respondent explained his educational background, including both his undergraduate and medical education. Tr. 71–73. Respondent also described his career in pediatrics. *Id.* at 75–78. Respondent testified that he is currently married with two eleven-year-old children and that they are a ''very loving family.'' *Id.* at 48. Respondent also confirmed that he committed the crime to which he pled guilty. *Id.* Respondent testified that he had been having financial difficulties as a solo practitioner at the time but that it was not an excuse for what he did. *Id.* at 97. Respondent testified that a friend who worked for BLS as a representative introduced him to BLS and initiated Respondent's arrangement with BLS. *Id.* at 64. Respondent stated that he referred his laboratory specimens to BLS and in exchange he would receive $2,000–$4,000 [1] in cash on a monthly basis and trips to a strip club with his brother a few times a year.[2] *Id.* at 48–49, 60–61, 63, and 65. Regarding his non-monetary remuneration, he testified, ''So what I received was of course we would eat there. I mean they had typical—it was a restaurant in there. And alongside that, it would be a lap dance.'' *Id.* at 60. Respondent's friend who introduced him to BLS was the one who brought Respondent the monthly payments at Respondent's office. *Id.* at 64–66. The monthly payments varied but did not depend on anything in particular like how much lab work Respondent sent to BLS. *Id.* at 65. Respondent testified that his wife did not know about his arrangement with BLS, however, his wife knew that he was going out with the owners of BLS to a strip club and Respondent and his wife have nonetheless maintained a good and trusting relationship. *Id.* at 62–63 and 66. Respondent also testified that he was ''not exclusive to BLS.'' *Id.* at 49. Respondent sent approximately 40% of his lab work to BLS and Respondent and his brother received a combined total of $175,000, of which Respondent received half. *Id.* at 49 and 99. Respondent stated that he knew that referring the blood samples to BLS was wrong at the time that he was doing it. *Id.* As far as his protocol for deciding whether to send blood samples to BLS or other laboratories, Respondent testified that he rotated laboratories to compare the blood results amongst the different laboratories. *Id.* at 49–50. On cross examination, Respondent testified that the arrangement with BLS ended when BLS was arrested by the federal government and that he did not know the approximate number of patients that he had referred to BLS throughout the duration of the arrangement. *Id.* at 95.

Respondent testified that he was never charged with doing any unnecessary testing and that there was no additional expense to the patients, insurance companies, or the government. *Id.* at 50 and 80. Respondent also testified that although BLS was not a reputable company and what they did was ''terrible'' their blood testing was normal and comparable with other laboratories. *Id.* at 95–96. Other than the present case, Respondent has never been in trouble with the law. *Id.* at 50. Additionally, Respondent has made all of the payments required as part of his plea agreement. *Id.* at 82. During cross examination, Respondent confirmed that he appealed his exclusion ''with regards to [his] extent of the blame for the exclusion'' and described his attempt to lessen the time period of the exclusion. *Id.* at 84 and 87. Respondent also confirmed that he was aware of the aggravating factors that contributed to his long exclusion period, including the financial loss to government agencies of $50,000 or more, his conviction lasting more than two years, and his sentence including a period of incarceration. *Id.* at 88. Respondent stated that he didn't believe it was unreasonable to receive an exclusion, but that he thought it was an ''excessive'' exclusion. *Id.* at 88–89.

Respondent is currently licensed without restriction but is subject to probation for five years and has to have a practice monitor for 24 months. *Id.* The practice monitor is board-certified in internal medicine. *Id.* at 75. Before he was convicted and excluded from federal health care programs, Respondent had a pediatric practice. *Id.* at 51. Respondent stated that he wants to return to pediatrics but that because of his exclusion from federal health care programs, he is having issues being credentialed by private insurance companies, which insure the majority of his patients. *Id.* at 66–68. Respondent has also lost his previous hospital admitting privileges. *Id.* at 77. Additionally, Respondent was previously certified by the American Board of Pediatrics but because of his felony conviction, was suspended. *Id.* at 73–74. Respondent stated that he petitioned to be reinstated but because of the condition on his license that he has to have a practice monitor, he was unsuccessful. *Id.* at 74. Respondent confirmed that his petition was unsuccessful only because of the practice monitor requirement and not because of any issues with his level of practice. *Id.* Respondent also mentioned that he receives ''many phone calls'' asking him to return to pediatric practice. *Id.* at 79.

In the time since his medical license was reinstated in August 2019, Respondent has only been actively practicing medicine as of October 2020. *Id.* at 92. Respondent currently has an aesthetics wellness practice with his brother that offers aesthetic services, hormone replacement, and medical weight loss and Respondent has ''trained in many courses'' regarding aesthetics wellness. *Id.* at 51–53. Respondent testified that he would need a DEA registration to keep the practice running because he needs to prescribe

[1] The RD noted that Respondent's testimony in which Respondent first stated that the cash payments were ''always the same amount'' but then went on to state that the cash payments ranged from $2,000–$4,000 as an example of Respondent's lack of candor. RD, at 5; Tr. 65. It is difficult to tell from the record whether Respondent was just clarifying that the payments were not based on a particular factor when he stated that they were ''always the same amount,'' but the Chief ALJ then asked him on what the range depended and he stated, ''There was nothing—it would vary. That's all I would say.'' Tr. 65. I agree with the Chief ALJ that these statements do not appear to be fully forthcoming and should be considered as relevant to Respondent's acceptance of responsibility.

[2] On cross examination, Respondent was questioned regarding the specific services he and his brother were given during the trips to strip clubs provided by BLS because while in his testimony he had indicated that they were only given lap dances, in the plea agreement that he had signed, it was indicated that they had received lap dances and sexual acts. *Id.* 110–114. During this line of questioning, Respondent testified that they had only received lap dances, that ''sex acts'' referred only to lap dances, and that regarding the ambiguity of the wording involved with the plea agreement, he had simply signed what he was told to sign by his attorney. *Id.*

testosterone for hormone replacement and because it's ''very difficult to earn a living without [the] DEA license.'' *Id.* at 53–55. On cross examination, Respondent testified that he has not partnered with any other medical professionals in situations where his patients need controlled substances, so if a patient needs a controlled substance, Respondent will deny them service. *Id.* at 92–93. Respondent also confirmed that he would not have a need to prescribe opioid drugs or benzodiazepine drugs. *Id.* at 94. When questioned by the Chief ALJ if he would need the DEA registration for other reasons like malpractice insurance or credentialing, Respondent said he would not and that he did not have any issues with malpractice insurance. *Id.* at 54.

Prior to his sentencing, Respondent spoke to the Richmond County Medical Society, which, although he was embarrassed, he felt was ''absolutely necessary'' to express how sorry he was to have ''betrayed them and . . . the profession.'' *Id.* at 69–70. Respondent stated that they all knew about his situation because it was all public and that they accepted and understood that he was trying to ''educate them not to fall into the same trap.'' *Id.* Respondent also stated that if he could ''do anything to take it back [he] would.'' *Id.* at 70. Respondent testified that while he was in prison for 18 months, his wife would send him weekly journals regarding ''pretty much all disciplines of medicine which [he] would actually keep up with.'' *Id.* at 55–56 and 98. Respondent also testified that there were other physicians with him in prison and that they formed a club and had discussions regarding medicine on a weekly basis. *Id.* at 56. Since his release from prison, Respondent has taken about 60 CME credits, received his opiate certificate, and taken a 12-week ethics course, the latter two of which were required by the Office of Professional Medical Conduct (OPMC). *Id.* at 56–59. Respondent stated that he brought shame to his family, friends, and patients and that ''there wasn't anybody that wasn't the victim both directly [and] indirectly.'' *Id.* at 81. Respondent said that he was ''not looking to go back in prison'' and that ''[o]ne day in prison is enough to teach anybody a lesson.'' *Id.* Respondent's father passed away while he was in prison and Respondent described the remorse he feels for not being able to tell his father how sorry he was for what he did. *Id.* Respondent stated that it's been very difficult for him to start his practice and that he's ''tried everything [he] can to feed [his] family.'' *Id.* Respondent stated that he will ''never compromise [his] position as long as [he has] been given this last chance to do the right thing'' and that ''[he] will do the right thing.'' *Id.* at 82. On cross examination, Respondent testified that even if he had financial difficulties in the future, ''[a]fter being in prison for [so] long'' he would not take another ''opportunity for financial enrichment.'' *Id.* at 98.

Respondent's testimony also included the authentication of Respondent's exhibits. *Id.* at 40–44. Regarding a determination order from the New York State Department of Health State Board for Professional Medical Conduct, Respondent testified that the Board referred to Respondent's ''special remorse for which [he] suffered financially.'' *Id.* at 70–71. Regarding Respondent's collection of support letters, Respondent testified that he had not solicited patients for the letters but that because his case was in the news and everyone found out about it, patients had come in and asked what they could do to help him. *Id.* at 44–45. Respondent also testified that, in regard to glaring similarities between the letters, he had only told his patients to ''speak the truth and how [they] [felt] about [him]'' and ''what [their] [experiences were] with [Respondent] treating [them] as patients.'' *Id.* at 45–46. Finally, Respondent testified that he had received ''many more character letters'' than those included in the collection submitted for this case. *Id.* at 47–48. On cross examination, Respondent confirmed that all of the letters were written in 2017 in response to his criminal conviction and that none of the letters were addressed to the court of the current matter. *Id.* at 106–107.

Having read and analyzed all of the record evidence, I agree with the RD that while Respondent was candid and credible in discussing his background and his personal remorse, Respondent's testimony in other areas raises concerns regarding Respondent's candor and thus reduces his credibility and the weight this decision gives to his testimony. RD, at 8. In particular, I find that Respondent's testimony regarding his reasons for seeking a DEA registration was confusing and ambiguous as to whether he intends to return to pediatrics or to continue with the aesthetics practice that he currently operates with his brother. Tr. 51–55 and 66–68; *see also* RD, at 7.[3] I also agree with the Chief ALJ that ''[Respondent's] own admission that he signed his plea agreement, not because it was all true, but because his attorney told him to, raises significant doubts as to the credibility of his testimony.'' [4] RD, at 8; *see also* Tr. 110–114. Finally, and as will be discussed in more detail below, the stark similarities between Respondent's patient support letters combined with Respondent's testimony that there was no coaching or even solicitation involved in their acquisition further raises concerns regarding Respondent's candor and thus further damages Respondent's credibility. RX 4; RD, at 6–7; Tr. 44–46.

II. Discussion

A. The Government's Position

In its Post-Hearing Brief, the Government argues that ''[a] respondent's mandatory exclusion from federal health care programs under 42 U.S.C. 1320a–7(a) provides grounds for denial under 21 U.S.C. § 824(a)(5)'' and notes that ''[i]t is undisputed that Respondent has been excluded from participation in Medicare, Medicaid, and all [f]ederal health programs pursuant to 42 U.S.C. 1320a–7(a) for a period of 13 years.'' Government's Post-Hearing Brief, at 6. Additionally, the Government argues that the denial of Respondent's application is the appropriate sanction and that even if Respondent's application were granted, it should be restricted because ''Respondent has not unequivocally accepted responsibility, but has instead attempted to downplay his misconduct'' and ''Respondent's misconduct is so egregious, that denial of his application is warranted notwithstanding any purported acceptance of responsibility.'' *Id.* at 6–7. Specifically, the Government alleges that Respondent failed to acknowledge a portion of the bribes he received (namely, that he received both lap dances and additional sex acts) and that Respondent downplayed his role in the bribery scheme by characterizing it as ''nothing more than an informal arrangement between old friends.'' *Id.* at 7–9. Moreover, the Government contends that ''[a]lthough Respondent's crimes are not related to the controlled substances act, his crimes are of a nature that should concern the Agency'' because ''[w]ere Respondent to accept

[3] I am not considering the purpose of his application for a DEA registration for any other reason than his inconsistent statements.

[4] In the recent decision *Keith A Jenkins, N.P.,* which found in favor of the Respondent, a similar issue regarding the Respondent signing something because his attorney advised it was raised. *Keith A Jenkins, N.P.,* 86 FR 35,339 (2021). However, the present case can be distinguished from *Jenkins* in that in the present case, the issue pertains to a major fact of the underlying crime, while in *Jenkins,* the Respondent entered an Alford plea of guilty as a strategic decision at the advice of his attorney regarding a particular legal element of his offense. *Id.* at 35,344.

cash payments to prescribe unlawful prescriptions, it would be challenging for DEA to detect.'' *Id.* at 9–10. Finally, the Government concludes that for the protection of the public, even if granted, Respondent's registration should be limited to only what he claims that he needs it for, namely testosterone prescriptions. *Id.* at 10.

B. Respondent's Position

In Respondent's Post-Hearing Brief, Respondent highlighted a Determination and Order of the New York State Department of Health which, after a hearing was held to determine if Respondent's New York medical license should be revoked following his conviction, denied the Department's request to revoke Respondent's license and instead, opted to suspend Respondent's license until he was released from incarceration, followed by five years of probation, the first two years including a practice monitor. Respondent's Post-Hearing Brief, at 3–4. Respondent's Post-Hearing Brief included a quote from the Determination and Order stating that ''[t]he Committee based [its] determination on the Respondent's personal statement accepting full responsibility.'' *Id.* at 4. The included quote also noted that ''Respondent also offered in mitigation letters from colleagues and patients and the testimony of [colleagues] to show his commitment to his pediatric practice.'' *Id.* Finally, the quote concluded, ''[t]he Hearing Committee credited the Respondent's expressions of remorse for enriching himself financially while participating in such a scheme and his remedial efforts in appearing before the Richmond County Medical Society to candidly discuss his unlawful acts.'' *Id.*

Respondent's Post-Hearing Brief went on to argue that Respondent was truly remorseful, as evidenced in part by his lecturing to other doctors about the mistake he made and how they should avoid it. *Id.* at 4–5. Respondent's Post-Hearing Brief also noted that no patient's care was ever compromised, that Respondent never performed any unnecessary tests, that the payments made by Medicare and other insurance entities were exactly the same as they would have been from any other lab, and that BLS never provided anything but ''top quality work.'' *Id.* at 5. Respondent's Post-Hearing Brief emphasized that Respondent has never had any trouble with the law and described Respondent as ''an old-fashioned doctor who besides providing excellent medical care to his patients, listened to his patients and never rushed them out of his office.'' *Id.* Moreover, Respondent's Post-Hearing Brief included excerpts from some of the patient letters that Respondent submitted as Exhibit 4 in this case to demonstrate ''the type of care Respondent provided to his patients and how they reflect his following the Hippocratic Oath.'' *Id.* at 5–8.

Respondent's Post-Hearing Brief then went on to describe Respondent's remedial efforts, including keeping up with medical journals while incarcerated, forming a club with other physicians while incarcerated, and, since his release from prison, taking CME courses, an Opiate course, and an ethics course. *Id.* at 8–9. Respondent's Post-Hearing Brief concluded by emphasizing Respondent's remorse once again, describing how Respondent has suffered from being incarcerated, from paying fines and forfeiture, and from embarrassing and hurting his family, community, and patients. *Id.* at 9. Respondent's Post-Hearing Brief highlighted that Respondent ''is now trying to turn his life around and become a productive member of society'' and that to do this, he needs a DEA license for his aesthetics practice, because he is no longer able to practice pediatrics because he cannot get insurance. *Id.* Finally, Respondent's Post-Hearing Brief included an excerpt of Respondent's testimony in which Respondent reiterated his remorse, stated that he needed the DEA license to continue practicing medicine, and testified that even if he faced financial difficulties in the future, he would never again take similar actions because of the disgrace he brought to his family, friends, and patients and because he had learned his lesson by going to prison. *Id.* at 9–10.

C. Analysis of Respondent's Application for Registration

In this matter, the OSC calls for my adjudication of the application for registration based on the charge that Respondent was excluded from participation in a program pursuant to section 1320a–7(a) of Title 42, which is a basis for revocation or suspension under 21 U.S.C. 824(a)(5). OSC, at 1–2.

Prior Agency decisions have addressed whether it is appropriate to consider a provision of 21 U.S.C. 824(a) when determining whether or not to grant a practitioner registration application. For over forty-five years, Agency decisions have concluded that it is. *Robert Wayne Locklear, M.D.,* 86 FR at 33,744–45 (collecting cases); *see also, William Ralph Kincaid.* In the recent decision *Robert Wayne Locklear, M.D.,* the former Acting Administrator stated his agreement with the results of these past decisions and reaffirmed that a provision of section 824 may be the basis for the denial of a practitioner registration application. 86 FR at 33,745. He also clarified that allegations related to section 823 remain relevant to the adjudication of a practitioner registration application when a provision of section 824 is involved. *Id.*

Accordingly, when considering an application for a registration, I will consider any actionable allegations related to the grounds for denial of an application under 823 and will also consider any allegations that the applicant meets one of the five grounds for revocation or suspension of a registration under section 824. *Id. See also Dinorah Drug Store, Inc.,* 61 FR 15,972, 15,973–74 (1996).

1. 21 U.S.C. 823(f): The Five 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, or conducting research with respect to 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. 21 U.S.C. 823(f).

In this case, it is undisputed that Respondent holds a valid state medical license and is authorized to dispense controlled substances in the State of New York where he practices. *See* GX 2.

Because the Government has not alleged that Respondent's registration is inconsistent with the public interest under section 823, and although I have considered 823, I will not analyze Respondent's application under the public interest factors. Therefore, in accordance with prior agency decisions,

I will move to assess whether the Government has proven by substantial evidence that a ground for revocation exists under 21 U.S.C. 824(a). *Supra* II.C.

2. 21 U.S.C. 824(a)(5): Mandatory Exclusion From Federal Health Care Programs Pursuant to 42 U.S.C. 1320a–7(a)

Under Section 824(a) of the Controlled Substances Act (hereinafter, CSA), a registration ''may be suspended or revoked'' upon a finding of one or more of five grounds. 21 U.S.C. 824. The ground in 21 U.S.C. 824(a)(5) requires that the registrant ''has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of Title 42.'' *Id.* Here, there is no dispute in the record that Respondent is mandatorily excluded from federal health care programs under 42 U.S.C. 1320a–7(a). The Government has presented substantial evidence of Respondent's exclusion and the underlying criminal conviction that led to that exclusion, and Respondent has admitted to the same. GX 5; GX 7–8; Respondent's Post-Hearing Brief, at 2–3. Accordingly, I will sustain the Government's allegation that Respondent has been excluded from participation in a program pursuant to section 1320a–7(a) of Title 42 and find that the Government has established that a ground exists upon which a registration could be revoked pursuant to 21 U.S.C. 824(a)(5).[5] Although the language of 21 U.S.C. 824(a)(5) discusses suspension and revocation of a registration, for the reasons discussed above, it may also serve as the basis for the denial of a DEA registration application. *Dinorah Drug Store, Inc.,* 61 FR at 15,973 (interpreting 21 U.S.C. 824(a)(5) to serve as a basis for the denial of a registration because it ''makes little sense . . . to grant the application for registration, only to possibly turn around and propose to revoke or suspend that registration based on the registrant's exclusion from a Medicare program''). Respondent's exclusion from participation in a program under 42 U.S.C. 1320a–7(a), therefore, serves as an independent basis for denying his application for DEA registration. 21 U.S.C. 824(a)(5).

Here, there is no dispute in the record that Respondent is mandatorily excluded pursuant to Section 1320a–7(a) of Title 42 and, therefore, that a ground for the revocation or suspension of Registrant's registration exists. 21 U.S.C. 824(a)(5).

Where, as here, the Government has met its *prima facie* burden of showing that a ground for revocation exists, the burden shifts to the Respondent to show why he can be entrusted with a registration. *See Jeffrey Stein, M.D.,* 84 FR 46,968, 46,972 (2019).

III. Sanction

The Government has established grounds to deny a registration; therefore, I will review any evidence and argument the Respondent submitted to determine whether or not the 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. *Drug Enf't Admin.,* 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 Samuel S. Jackson, D.D.S.,* 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).

A. Acceptance of Responsibility

In evaluating the degree required of a respondent's acceptance of responsibility to entrust him with a registration, in *Mohammed Asgar, M.D.,* the Agency looked for ''unequivocal acceptance of responsibility when a respondent has committed knowing or intentional misconduct.'' 83 FR 29,569, 29,572 (2018) (citing *Lon F. Alexander, M.D.,* 82 FR 49,704, 49,728). Here, the Respondent stated that he knew at the time that he did it that it was wrong. Tr. 49. I will, therefore, look for a clear acceptance of responsibility from Respondent.

Respondent is clearly remorseful for his conduct, with Respondent emphasizing how he had brought shame to his family, friends, and patients and that ''there wasn't anybody that wasn't the victim both directly [and] indirectly.'' Tr. 81. He does seem to acknowledge that there are many victims, although his statements do not show any particular understanding of his crime or its impact. However, remorse and acceptance of responsibility are not the same thing, and although Respondent acknowledged that his patients had suffered, Respondent's focus on his own suffering does not suggest an unequivocal acceptance of responsibility, but rather, suggests that what he regrets most are the negative consequences that he has personally faced. As the Chief ALJ noted, Respondent ''freely admits that the ramifications of getting caught and punished has visited an extreme level of inconvenience and misfortune.'' RD, at 13. In particular, much of Respondent's testimony focused on how much of an impact his incarceration had had on him, with Respondent testifying that ''[o]ne day in prison is enough to teach anybody a lesson'' and describing the remorse he had felt about not being able to tell his father how sorry he was for what he did because his father had passed away while he was incarcerated. Tr. 81. Respondent also mentioned how difficult it has been for him to start a new practice following his incarceration. *Id.* Regarding whether, if faced with financial difficulties in the future, he would take another ''opportunity for financial enrichment'', Respondent testified that ''[a]fter being in prison for [so] long'' he would not, suggesting that the fear of incarceration, rather than genuine regret for the harm he has caused, is what would deter him from similar misconduct in the future. *Id.* at 98.

Additionally, there are points of Respondent's testimony and actions in the record that suggest attempts to downplay his mistakes. As the Chief ALJ pointed out, ''[t]he Respondent here essentially admitted to those things which he dared not deny. He admitted he was convicted and excluded from Medicare, but presented testimony that

[5] The Government correctly argues, and Respondent did not rebut, that the underlying conviction forming the basis for a registrant's mandatory exclusion from participation in federal health care programs need not involve controlled substances to provide the grounds for revocation or denial pursuant to section 824(a)(5). *Jeffrey Stein, M.D.,* 84 FR 46,968, 46,971–72 (2019); *see also Narciso Reyes, M.D.,* 83 FR 61,678, 61,681 (2018); *KK Pharmacy,* 64 FR 49,507, 49,510 (1999) (collecting cases); *Melvin N. Seglin, M.D.,* 63 FR 70,431, 70,433 (1998); *Stanley Dubin, D.D.S.,* 61 FR 60,727, 60,728 (1996).

was equivocal and confusing regarding the details.'' RD, at 13. Respondent testified that he was never charged with doing any unnecessary testing, that there was no additional expense to the patients, insurance companies, or the government, and that, although BLS was not a reputable company and what they did was ''terrible,'' their blood testing was normal and comparable with other laboratories.[6] *Id.* at 50, 80, 95–96. Respondent repeatedly minimized his characterization of the non-monetary remunerations he received and even when confronted with the plain language of his plea agreement. *See supra* n.2; Tr. 60, 62; RD, at 13. Also, Respondent confirmed that he had appealed his exclusion from federal healthcare programs because, although he had understood the aggravating factors, he had also thought his long exclusion period was ''excessive,'' but he did not explain further the rationale for this belief or why the exclusion period was so long initially. *Id.* at 84 and 87–89. I do credit Respondent for stating, ''I just did it. I mean, I have no excuse.'' *Id.* at 97. However, ''the degree of acceptance of responsibility that is required does not hinge on the respondent uttering 'magic words' of repentance, but rather on whether the respondent has credibly and candidly demonstrated that he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator.'' *Stein,* 84 FR at 46,973.

Overall, Respondent's focus on himself and his minimization of his wrongdoings and the issues with his credibility suggest that he has not credibly and unequivocally accepted responsibility for his actions and the harm that he caused. *See id.* at 46,972 (finding that a registrant's attempts to minimize his misconduct weigh against a finding of unequivocal acceptance of responsibility).

Even if Respondent's acceptance of responsibility for his wrongdoing had been sufficient such that I would reach the matter of remedial measures, Respondent has not offered adequate remedial measures to assure me that I can entrust him with a registration. *See Carol Hippenmeyer, M.D.,* 86 FR 33,748, 33,773 (2021). Prior to his sentencing, Respondent spoke to the Richmond County Medical Society about his crime.[7] Tr. 69–70. While in prison, Respondent kept up with medical journals and formed a club with other physicians to discuss medicine. Tr. 55–56. Since his release, Respondent has taken about 60 hours in continuing medical educations courses (CME),[8] gotten his opiate certificate, and taken a 12-week ethics course.[9] *Id.* at 56–59. Given the circumstances and in comparison to the similar case in *Martinho,* I find that Respondent's remedial efforts have been minimal and thus insufficient to ensure that Respondent can be trusted with registration.

B. Specific and General Deterrence

In addition to acceptance of responsibility, the Agency gives consideration to both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,810 (2015). Specific deterrence is the DEA's interest in ensuring that a registrant complies with the laws and regulations governing controlled substances in the future. *Id.* General deterrence concerns the DEA's responsibility to deter conduct similar to the proven allegations against the respondent for the protection of the public at large. *Id.* Where a respondent has committed a crime with no nexus to controlled substances, it is sometimes difficult to demonstrate that a sanction will have a useful deterrent effect. In this case, I believe a sanction of denial of the application would deter Respondent and the general registrant community from unethical behavior and deceit, particularly involving the acceptance of money for unlawful and unethical acts. It is not difficult to imagine, as the Agency has repeatedly encountered, this situation repeating itself in the context of receiving money for controlled substance prescriptions. ''Deterring such deceit and knowing criminal behavior both in Respondent and the general registrant community is relevant to ensuring compliance with the CSA.'' *Ibrahim Al-Qawaqneh, D.D.S.,* 86 FR 10,354, 10,357 (2021).

C. Egregiousness

The Agency also looks to the egregiousness and the extent of the misconduct as significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.,* 83 FR at 18,910 (collecting cases). In this case, Respondent knew that his arrangement with BLS was wrong but accepted the arrangement anyway and kept it going from October 2010 to March of 2013, because he had been having financial difficulties as a solo practitioner. Tr. 95. The arrangement was a blatant kickback scheme involving substantial monetary payments.[10] In addition, the arrangement was both periodic and ongoing for multiple years, giving Respondent plenty of opportunity to correct course, but there is nothing in the record to indicate that he had any intention of ending the arrangement. *See also* RD, at 14. After receiving 2 to 4 thousand dollars per month, *Id.* at 65, there must have been a point at which he was no longer facing financial difficulties, and yet he continued until ''the laboratory got arrested by the federal government.'' Tr. 95. Furthermore, the exclusion letter notes that HHS/OIG deemed Respondent's criminal misconduct egregious enough to warrant an exclusion period in excess of the statutory minimum. GX 7, at 2. The exclusion letter explains that HHS/OIG excluded Respondent for thirteen years instead of the statutory minimum of five years because (1) Respondent's misconduct caused or was intended to cause financial loss of more than $50,000 to a government agency or program; (2) Respondent committed the misconduct over a period of at least a year; and (3) Respondent's sentence included incarceration. *Id. See Michael Jones, M.D.,* 86 FR 20,728, 20,732 (2021) (considering the length of the HHS

[6] It is also noted that Respondent provided no support for the statement that the testing was normal and comparable in the record.

[7] I commend Respondent on his attempts to have a deterrent effect on his colleagues and community. In *Martinho,* the former Acting Administrator considered this type of engagement in determining that a respondent who had been excluded from federal healthcare programs for accepting similar kickbacks for laboratory referrals could be entrusted with a registration; however, the facts of *Martinho* are very distinct from the facts on the present record. *Michele L. Martinho, M.D.,* 86 FR 24,012, 24,019 (2021). The respondent in that case had dedicated herself to self-described ''restorative justice'' well beyond what was required by her probation—engaging in sixty-nine speaking engagements, which were featured in major news outlets. *Id.* Although her misconduct occurred for a similar amount of time and money, HHS penalized her with the minimum timeframe for exclusion, she engaged in a methodological survey to verify for her own conscience that she did not increase her blood draws and did not overstate that survey's value, she admitted that the lab had created insurance problems for her patients and tried to correct it, and importantly, she also fully, sincerely and credibly accepted responsibility for her actions, such that the prosecutor at her criminal sentencing stated that she '' 'had demonstrated a level of contrition that has been unique among the many, many doctors that we've dealt with in this case.' '' *Id.*

[8] Though Respondent testified to completing CME courses, he did not provide evidence to the record confirming the completion of the courses.

[9] As previously mentioned, the latter two were required by the Office of Professional Medical Conduct (OPMC). *Id.*

[10] Also, I am concerned about repeat behavior in this case because the wrongdoing appears to be influenced by social interactions. The fact that Respondent was first approached about the bribes by a ''friend of [his],'' Tr. 64, participated in the arrangement with his brother, and they all engaged in social activities together during which payments were received, does not inspire confidence that Respondent will take his responsibility to his patients and his ethical obligations seriously in the future.

exclusion in assessing egregiousness). As the Chief ALJ noted, ''on the record, the interests of general deterrence, like the egregiousness of the established conduct, support the imposition of the application denial sought by the Government.'' RD, at 15.

D. Letters of Support

My final item of consideration is the collection of nineteen letters that Respondent submitted from patients, colleagues, and friends to demonstrate his high level of care as a physician and his commitment to the Hippocratic Oath. Respondent's Post-Hearing Brief, at 5–8; RX 4. Although I find the letters to be sincere, they can only be of limited weight in this proceeding because of the limited ability to assess the credibility of the letters given their written form. *See Michael S. Moore, M.D.,* 76 FR 45,867, 45,873 (2011) (evaluating the weight to be attached to letters provided by the respondent's hospital administrators and peers in light of the fact that the authors were not subjected to the rigors of cross examination). Furthermore, these letters were not written for the purposes of recommending that Respondent be granted a controlled substances registration and therefore offer little value in assessing the Respondent's suitability to discharge the duties of a DEA registrant. *William Ralph Kinkaid, M.D.,* 86 FR 40,636, 40,641 (2021). Instead, Respondent's letters were used by his criminal defense counsel prior to his sentencing, with most of the letters dated back to 2017. RX 4; Tr. 106–107. Additionally, as the Chief ALJ noted, the ''recognizable pattern'' of the patient letters, in combination with Respondent's insistence that there was no suggested format and Respondent's testimony that he had not solicited patients for the letters, does raise questions as to whether there was any ''coaching or importuning'' involved in their collection and thus damages their credibility. RD, at 6–7; RX 4Tr. 44–46. The Chief ALJ did note that ''it would be difficult (and unjust) to ignore the volume of support/correspondence from his patients, or the often poignant accounts enshrined within those letters.'' RD, at 14. I agree and I note that the letters say many positive things about Respondent, however, I find that because Respondent has not demonstrated credible and unequivocal acceptance of responsibility, I cannot place weight on letters written in a different context in demonstrating that Respondent can be entrusted with a DEA registration, when he, himself, has not credibly done so. *See Kinkaid, M.D.,* 86 FR at 40,641.

As discussed above, to receive a registration when grounds for denial exist, a respondent must convince the Administrator that his acceptance of responsibility is sufficiently credible to demonstrate that the misconduct will not occur and that he can be entrusted with a registration. Having reviewed the record in its entirety, I find that Respondent has not met this burden. Although Respondent expressed remorse and took some responsibility for his actions through his guilty plea and his efforts at remediation, his acceptance of responsibility was not unequivocal. Respondent's focus on his own consequences and his minimization of his wrongdoings both raise concerns that he does not truly understand the severity of his misconduct. Further, Respondent's remediation efforts have been minimal and unpersuasive. As such, I am not convinced that Respondent would not commit similar misconduct again in the future if he believed that it would not result in negative consequences. Accordingly, I will order the denial of Respondent's application for a certificate of registration.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823, I hereby deny the pending application for a Certificate of Registration, Control Number W20041078C, submitted by George Roussis, M.D., as well as any other pending application of George Roussis, M.D., for additional registration in New York. This Order is effective December 6, 2021.

Anne Milgram,

Administrator.

[FR Doc. 2021–24205 Filed 11–4–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Agency Information Collection Activities; Comment Request; Request for Electronic Service of Orders—Waiver of Certified Mail Requirement

AGENCY: Division of Federal Employees', Longshore and Harbor Workers' Compensation, Office of Workers' Compensation Programs.

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Request for Electronic Service of Orders—Waiver of Certified Mail Requirement.'' 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 January 4, 2022.

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 for free by contacting Anjanette Suggs by telephone at 202–354–9660 or by email at *suggs.anjanette@dol.gov.*

Submit written comments about this ICR by mail or courier to the U.S. Department of Labor, Office of Workers' Compensation Programs, Room S3323, 200 Constitution Avenue NW, Washington, DC 20210; or by email at *suggs.anjanette@dol.gov.* Please note that comments submitted after the comment period will not be considered.

FOR FURTHER INFORMATION CONTACT: Anjanette Suggs by telephone at 202–354–9660 or by email at *suggs.anjanette@dol.gov.*

SUPPLEMENTARY INFORMATION: The 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 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.

The Office of Workers' Compensation Programs administers the Longshore and Harbor Workers' Compensation Act. The Act provides benefits to workers injured in maritime employment on the navigable waters of the United States or in an adjoining area customarily used by an employer in loading, unloading, repairing, or building a vessel. In addition, several acts extend the Longshore Act's coverage to certain other employees.

The Longshore and Harbor Workers' Compensation Act (LHWCA), at 33 U.S.C. 919(e), requires that any order rejecting or making an LHWCA award (the compensation order) be filed in the appropriate district director's office of

the Office of Workers' Compensation Programs (OWCP), and that copies be sent by registered or certified mail to the claimant and the employer. The implementing regulations at 20 CFR 702.349(b) allow parties and their representatives to waive certified mail service and consent to electronic service instead. The compensation order notifies Employers/Carriers that payment of LHWCA compensation is due within 10 days of filing. If compensation is not paid within that time frame, an additional 20% in compensation must be paid [see LHWCA 914(f)].

The information collected will be used by OWCP to more efficiently serve compensation orders by email instead of by registered or certified mail. Form LS–801 will be completed by the employer/insurance carrier and/or an authorized representative and forwarded to the District Director indicating waiver of service by registered or certified mail and designation of receipt by email instead. The LS–802 will be completed by the claimants and/or an authorized representative and forwarded to the District Director indicating waiver of service by registered or certified mail and designation of receipt by email instead. This information collection is currently approved for use through April 30, 2022.

Legal authority for this information collection is found at 33 U.S.C. 919(e).

Regulatory authority is found at 20 CFR 702.349(b) .

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB under the PRA approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid 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. Written comments will receive consideration, and summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB No. 1240–0053.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

The 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-Office of Workers' Compensation Programs, DFELHWC.

Type of Review: Extension of currently approved collection.

Title of Collection: Request for Electronic Service of Orders—Waiver of Certified Mail Requirement.

Form: LS–801, LS–802, Waiver of Service by Registered or Certified Mail for Employers and/or Insurance Carriers, Waiver of Service by Registered or Certified Mail for Claimants and Authorized Representatives.

OMB Control Number: 1240–0053.

Affected Public: Private Sector.

Estimated Number of Respondents: 9,240.

Frequency: On occasion.

Total Estimated Annual Responses: 9,240.

Estimated Average Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 767 hours.

Total Estimated Annual Other Cost Burden: $0.

(Authority: 44 U.S.C. 3506(c)(2)(A))

Anjanette Suggs,

Agency Clearance Officer.

[FR Doc. 2021–24272 Filed 11–4–21; 8:45 am]

BILLING CODE 4510–CF–P

OFFICE OF MANAGEMENT AND BUDGET

Senior Executive Service Performance Review Board Membership

AGENCY: Office of Management and Budget.

ACTION: Notice.

SUMMARY: The Office of Management and Budget (OMB) publishes the names of the members selected to serve on its Senior Executive Service (SES) Performance Review Board (PRB). This notice supersedes all previous notices of the PRB membership.

DATES: *Applicable:* November 1, 2021.

FOR FURTHER INFORMATION CONTACT: Sarah Whittle Spooner, Assistant Director for Management and Operations, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, 202–395–7402.

SUPPLEMENTARY INFORMATION: Section 4314(c) of Title 5, U.S.C. requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more PRBs. The PRB shall review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any response by the senior executive, and make recommendations to the final rating authority relative to the performance of the senior executive.

The persons named below have been selected to serve on OMB's PRB.

Rachel L. Wallace, Chief of Staff
David C. Connolly, Chief, Transportation and Services Branch, General Government Programs
Alexander T. Hunt, Chief, Information Policy Branch, Office of Information and Regulatory Affairs
Adrienne E. Lucas, Deputy Associate Director for Natural Resources Division
David J. Rowe, Deputy Assistant Director for Budget
Sarah Whittle Spooner, Assistant Director for Management and Operations

Sarah Whittle Spooner,

Assistant Director for Management and Operations.

[FR Doc. 2021–24127 Filed 11–4–21; 8:45 am]

BILLING CODE 3110–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

Meeting of National Council on the Humanities

AGENCY: National Endowment for the Humanities; National Foundation on the Arts and the Humanities.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the National Council on the Humanities will meet to advise the Chair of the National Endowment for the Humanities (NEH) with respect to policies, programs and procedures for carrying out his functions; to review applications for financial assistance under the National Foundation on the Arts and Humanities Act of 1965 and make recommendations thereon to the Chair; and to consider gifts offered to NEH and make recommendations thereon to the Chair.

DATES: The meeting will be held on Thursday, November 18, 2021, from 11:00 a.m. until 2:30 p.m., and Friday, November 19, 2021, from 11:00 a.m. until adjourned.

ADDRESSES: The meeting will be held by videoconference originating at Constitution Center, 400 7th Street SW, Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW, 4th Floor, Washington, DC 20506; (202) 606–8322; *evoyatzis@neh.gov.*

SUPPLEMENTARY INFORMATION: The National Council on the Humanities is meeting pursuant to the National Foundation on the Arts and Humanities Act of 1965 (20 U.S.C. 951–960, as amended). The following Committees of the National Council on the Humanities will convene by videoconference on November 18, 2021, from 11:00 a.m. until 2:30 p.m., to discuss specific grant applications and programs before the Council: Challenge Programs; Digital Humanities; Education Programs; Federal/State Partnership; Preservation and Access; Public Programs; and Research Programs.

The plenary session of the National Council on the Humanities will convene by videoconference on November 19, 2021, at 11:00 a.m. until 12:40 p.m. The agenda for the plenary session will be as follows:

A. Minutes of Previous Meetings
B. Reports
1. Acting Chair's Remarks
2. Chief of Staff's Remarks
3. Reports on Policy and General Matters
C. Challenge Programs
D. Digital Humanities
E. Education Programs
F. Federal/State Partnership
G. Preservation and Access
H. Public Programs
I. Research Programs

The National Council will then convene in executive session by videoconference on November 19, 2021, from 12:45 p.m. to 2:15 p.m.

This meeting of the National Council on the Humanities will be closed to the public pursuant to sections 552b(c)(4), 552b(c)(6), and 552b(c)(9)(B) of Title 5 U.S.C., as amended, because it will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, and discussion of certain information, the premature disclosure of which could significantly frustrate implementation of proposed agency action. I have made this determination pursuant to the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings dated April 15, 2016.

Dated: November 2, 2021.

Samuel Roth,

Attorney-Advisor, National Endowment for the Humanities.

[FR Doc. 2021–24273 Filed 11–4–21; 8:45 am]

BILLING CODE 7536–01–P

OFFICE OF THE DIRECTOR OF NATIONAL INTELLIGENCE

Privacy Act of 1974; System of Records

AGENCY: Office of the Director of National Intelligence (ODNI)

ACTION: Notice of a revised system of records.

SUMMARY: ODNI provides notice of a revision to a Privacy Act system of records at the National Counterintelligence and Security Center (NCSC). This notice revises the system of records titled Continuous Evaluation Records, also identified as ODNI/NCSC–003. This notice is necessary to inform the public of revisions to the notice summary, system purpose, categories of individuals covered, and supplementary information about the records that the agency maintains. This revised notice to the Continuous Evaluation (CE) Records system adds one-time record checks of employment applicants in addition to the previous uses of CE for enrolled individuals.

CE is a personnel security investigative process used to review the continued eligibility of individuals who have been determined eligible for access to classified information or to hold a sensitive position. Individuals subject to CE include current Executive Branch employees, detailees, contractors, and other sponsored individuals who are cleared for access to classified information or to hold a sensitive position. The Departments and Agencies (D/A) that sponsor these individuals for access to classified information or to hold a sensitive position ''enroll'' the individuals (enrollees) by electronically entering their identifying information into the CE System, an information technology system that conducts automated checks of security-relevant information.

All D/As are required to submit their qualifying populations for CE automated record checks. D/As may choose to develop a CE system of their own, or subscribe to CE services provided by another agency. NCSC will provide CE services to subscribing agencies via the ODNI CE System. The CE System conducts automated checks of government and commercial databases and, based on personnel security business rules, transmits electronic alerts and reports to the subscribing agency. Databases queried in the CE process are those that contain security-relevant information, *e.g.,* government-owned financial, law enforcement, terrorism, foreign travel, and current clearance status information. Credit bureau records and commercially-aggregated publically available data are also used. On receipt of an electronic alert or report, authorized personnel security officials at the subscribing agency verify that the alert or report received pertains to the enrollee (the subject of the electronic queries). Where the agency verifies that the alert or report pertains to the enrollee, authorized personnel security officials review the nature of the alert or report to determine the need for further investigation, as dictated by Federal Investigative Standards requirements. Information obtained through any follow-on investigation is considered in adjudicating the enrollee's continued eligibility for access to classified information or to hold a sensitive position.

The ODNI CE System retains the enrollment information (personal identifiers provided by the subscribing agency to facilitate ongoing CE checks for individuals who are enrolled in the CE System. The system does not retain the records returned from the electronic database queries beyond the time

needed to ensure proper electronic delivery to the subscribing agency. Data necessary to implement CE business rules, to perform program assessments, and to satisfy auditing requirements will be retained. D/As conducting CE will adhere to the principles articulated in Security Executive Agent Directive (SEAD) 6, *Continuous Evaluation.* SEAD 6 establishes policy and provides high-level guidance and requirements specific to the personnel security investigative process.

The CE System is being revised to now also conduct one-time electronic record checks for initial vetting of individuals seeking Executive Branch employment that requires eligibility for access to classified information or to hold a sensitive position. Employment applicants receiving one-time checks of security-relevant information are not enrolled in the CE System for ongoing record checks, and personal identifiers and records returned are only retained in the system for the time needed to ensure proper electronic delivery to the subscribing agency.

DATES: This revised System of Records Notice will go into effect on November 5, 2021, unless comments are received that result in a contrary determination.

ADDRESSES: You may submit comments by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov.

Email: transparency@dni.gov.

Mail: Director, Information Management Office, Chief Operating Officer, ODNI, Washington, DC 20511.

SUPPLEMENTARY INFORMATION: The ODNI CE System provides the technical capability to conduct automated record checks pursuant to Public Law 114–113, 5 U.S.C. 11001 (*Enhanced Personnel Security Programs*); Executive Order 12968, as amended (*Access to Classified Information*); Executive Order 13467, as amended, (*Reforming Processes Related to Suitability for Government Employment, Fitness for Contractor Employees, and Eligibility for Access to Classified National Security Information*), and; Executive Order 13764 (*Amending the Civil Service Rules, Executive Order 13488, and Executive Order 13467 to Modernize the Executive Branch-Wide Governance Structure and Processes for Security Clearances, Suitability and Fitness for Employment, and Credentialing, and Related Matters*).

To protect classified and sensitive personnel or law enforcement information covered by this system of records, the Director of National Intelligence (DNI) has exempted this system from certain requirements of the Privacy Act where necessary, as permitted by law. By previously established rule, the DNI may exempt records contained in this system of records from the requirements of subsections (c)(3), (d)(1), (d)(2), (d)(3), (d)(4), (e)(1), (e)(4)(G), (H), (I), and (f) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(1), (k)(2) and (k)(5). Additionally, the DNI may exercise derivative exemption authority by preserving the exempt status of records received from providing agencies when the reason for exemption remains valid. See 32 CFR part 1701.20 (a)(2) (73 FR 16531, 16537).

SYSTEM NAME AND NUMBER:

Continuous Evaluation Records (ODNI/NCSC–003).

SECURITY CLASSIFICATION:

The classification of records in this system ranges from UNCLASSIFIED to TOP SECRET.

SYSTEM LOCATION:

National Counterintelligence and Security Center, Office of the Director of National Intelligence, Washington, DC 20511.

SYSTEM MANAGER(S):

Assistant Director, Special Security Directorate, ODNI/NCSC, Washington, DC 20511.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Intelligence Reform and Terrorism Prevention Act of 2004, Public Law 108–458, 118 Stat. 3638 (Dec. 17, 2004); the National Security Act of 1947, as amended, 50 U.S.C. 3023 *et seq.;* the Counterintelligence Enhancement Act of 2002, as amended, 50 U.S.C. 3382; Executive Order 12333, 46 FR 59941 (1981), as amended by Executive Order 13284, 68 FR 4075 (2003), Executive Order 13355, 69 FR 53593 (2004), and Executive Order 13470, 73 FR 45325 (2008); Executive Order 13488, 74 FR 4111 (2009), as amended by Executive Order 13764, 82 FR 8115 (2017); Executive Order 13549, 75 FR 51609 (2010); Executive Order 12968, 60 FR 40245 (1995), as amended by Executive Order 13467, 73 FR 38103 (2008), and Executive Order 13764, 82 FR 8115 (2017); Executive Order 13467, as amended by Executive Order 13764 82 FR 8115 (2017).

PURPOSE(S) OF THE SYSTEM:

Records in this system of records are collected for the purpose of electronically comparing an individual's identifying data against specified U.S. Government (financial, law enforcement, terrorism, foreign travel, and clearance status) databases and credit bureau and commercial public records databases. The comparison serves to identify security-relevant conduct, practices, activities, or incidents that personnel security officials evaluate, consistent with the Federal Investigative Standards, to determine a CE enrollee's initial and continued eligibility for access to classified information or to hold a sensitive position. Additionally, one-time record checks of employment applicants may be conducted using data within the CE system.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Executive Branch employees, detailees, contractors, and other sponsored individuals who have been determined to be eligible for access to classified information or eligible to hold a sensitive position; applicants seeking Executive Branch employment that requires eligibility for access to classified information or to hold a sensitive position.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system maintains: (i) Biographic enrollment data including name, date and place of birth, Social Security number, gender, current address, other first or last names, prior address(es), personal email address(es), personal phone numbers, passport information, employment type (contractor/government) or other status, and; (ii) data returned from or about the automated record checks conducted against current clearance status information and against financial, law enforcement, credit, terrorism, foreign travel, and commercial databases.

RECORD SOURCE CATEGORIES:

Record source categories include government-owned financial, law enforcement, terrorism, foreign travel databases, and current clearance status information, as well as credit and commercial entities, and providers of aggregated public source data.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, these records may specifically be disclosed outside ODNI as a routine use pursuant to 5 U.S.C. 552a(b)(3), and as contained in the ODNI rule implementing the Privacy Act, 32 CFR part 1701 (73 FR 16531)as follows:

(i) Except as noted on Standard Forms 85 and 86 and supplemental forms thereto (questionnaires for employment in, respectively, ''non-sensitive'' and

''national security'' positions within the federal government), a record that on its face or in conjunction with other information indicates or relates to a violation or potential violation of law, whether civil, criminal, administrative, or regulatory in nature, and whether arising by general statute, particular program statute, regulation, rule, or order issued pursuant thereto, may be disclosed as a routine use to an appropriate federal, state, territorial, tribal, local law enforcement authority, foreign government, or international law enforcement authority, or to an appropriate regulatory body charged with investigating, enforcing, or prosecuting such violations;

(ii) A record from a system of records maintained by ODNI may be disclosed as a routine use to representatives of another Intelligence Community (IC) entity addressing intelligence equities in the context of a legislative proceeding or hearing when ODNI interests are implicated, and the record is relevant and necessary to the matter;

(iii) A record from a system of records maintained by ODNI may be disclosed as a routine use in a proceeding before a court or adjudicative body when any of the following is a party to litigation or has an interest in such litigation, and the ODNI Office of General Counsel determines that use of such records is relevant and necessary to the litigation: ODNI; any staff of ODNI in his/her official capacity; any staff of ODNI in his/her individual capacity where the Department of Justice has agreed to represent the staff or has agreed to provide counsel at government expense; or the United States or another federal agency, where the ODNI Office of General Counsel determines that litigation is likely to affect the ODNI;

(iv) A record from this system of records may be disclosed to the Department of Justice when: (a) ODNI, or any component thereof; or (b) any employee of ODNI in his/her official capacity; or (c) any employee of ODNI in his/her individual capacity where the Department of Justice has agreed to represent the employee; or (d) the United States, where ODNI determines that litigation is likely to affect the agency, or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice is deemed by the agency to be relevant and necessary to the litigation provided, however, that in each case, the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

(v) A record from a system of records maintained by ODNI may be disclosed as a routine use to representatives of the Department of Justice and other U.S. Government entities, to the extent necessary to obtain advice on any matter within the official responsibilities of such representatives, and the responsibilities of ODNI;

(vi) A record from a system of records maintained by ODNI may be disclosed as a routine use to a federal, state, or local agency or other appropriate entities or individuals from which/whom information may be sought relevant to: a decision concerning the hiring or retention of an employee or other personnel action; the issuing or retention of a security clearance or special access, contract, grant, credential, or other benefit; or the conduct of an authorized investigation or inquiry, to the extent necessary to identify the individual, inform the source of the nature and purpose of the inquiry, and identify the type of information requested;

(vii) A record from a system of records maintained by ODNI may be disclosed as a routine use to any federal, state, local, tribal, or other public authority, or to a legitimate agency of a foreign government or international authority to the extent the record is relevant and necessary to the other entity's decision regarding the hiring or retention of an employee or other personnel action, the issuing or retention of a security clearance or special access, contract, grant, license, or other benefit, or the conduct of an authorized inquiry or investigation;

(viii) A record from a system of records maintained by ODNI may be disclosed as a routine use to any agency, for authorized audit operations, and for meeting-related reporting requirements, including disclosure to the National Archives and Records Administration for records management inspections and such other purposes conducted under the authority of 44 U.S.C. 2904 and 2906, or successor provisions;

(ix) A record from a system of records maintained by ODNI may be disclosed as a routine use to contractors, grantees, experts, consultants, or others when access to the record is necessary to perform the function or service for which they have been engaged by the ODNI;

(x) A record from the Continuous Evaluation system of records maintained by ODNI may be disclosed as a routine use to any federal agency that has provided employee enrollment data to ODNI for purposes of conducting continuous evaluation when records obtained by ODNI are relevant to the subscribing agency's adjudication of the employee's continued eligibility for access to classified information or to hold a sensitive position.

(xi) A record from a system of records maintained by ODNI may be disclosed as a routine use to appropriate agencies, entities, and persons when: (1) ODNI suspects or has confirmed that there has been a breach of the system of records; (2) ODNI has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, ODNI (including its information systems, programs, and operations), the federal government, or national security, and; (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(xii) A record from a system of records maintained by ODNI may be disclosed as a routine use to another federal agency or federal entity, when the ODNI determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in: (1) responding to a suspected or confirmed breach, or; (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the federal government, or national security, resulting from a suspected or confirmed breach.

(xiii) A record from a system of records maintained by ODNI may be disclosed as a routine use to a federal, state, local, tribal, territorial, foreign, or multinational agency or entity or to any other appropriate entity or individual for any of the following purposes: To provide notification of a serious terrorist threat for the purpose of guarding against or responding to such threat; to assist in coordination of terrorist threat awareness, assessment, analysis, or response, or; to assist the recipient in performing authorized responsibilities relating to terrorism or counterterrorism;

(xiv) A record from a system of records maintained by ODNI may be disclosed as a routine use for the purpose of conducting or supporting authorized counterintelligence activities as defined by section 3003(3) of the National Security Act of 1947, as amended, to elements of the IC, as defined by section 3003(4) of the National Security Act of 1947, as amended, to the head of any federal agency or department, and to selected

counterintelligence officers within the federal government, and;

(xv) A record from a system of records maintained by ODNI may be disclosed as a routine use to a federal, state, local, tribal, territorial, foreign, or multinational government agency or entity, or to other authorized entities or individuals, but only if such disclosure is undertaken in furtherance of responsibilities conferred by, and in a manner consistent with: the National Security Act of 1947, as amended; the Counterintelligence Enhancement Act of 2002, as amended; Executive Order 12333 or any successor order together with its implementing procedures approved by the Attorney General, and; other provisions of law, Executive Order or directive relating to national intelligence, or otherwise applicable to ODNI. This routine use is not intended to supplant the other routine uses published by the ODNI.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic records are stored in secure file-servers located in government-managed facilities on secure private cloud-based systems that are connected only to a government network.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

The records in this system are retrieved by name, Social Security number, or other unique identifier. Information may be retrieved from this system of records by automated capabilities used in the normal course of business. All searches of this system of records are performed by authorized Executive Branch security personnel.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Pursuant to 44 U.S.C. 3303a(d) and 36 CFR Chapter 12, Subchapter B—Records Management, CE records about applicants seeking Executive Branch employment that requires eligibility for access to classified information or to hold a sensitive position; and CE records about Executive Branch employees, detailees, contractors, and other sponsored individuals who have been determined to be eligible for access to classified information or eligible to hold a sensitive position; are covered by the National Archives and Records Administration (NARA) General Records Schedule (GRS) 5.6, Security Records. All CE records will be retained and disposed of according to the applicable NARA GRS provisions. Biographic data and data about protecting and accessing information will be retained consistent with the Privacy Act of 1974, 5 U.S.C. 552a, and GRS 4.2, Information Access and Protection Records. Records about security data and information systems are listed in GRS 3.2, Information Systems Security Records.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Information in this system is safeguarded in accordance with recommended and/or prescribed administrative, physical, and technical safeguards. Records are maintained in secure government-managed facilities with access limited to authorized personnel. Physical security protections include guards and locked facilities requiring badges and passwords for access.

Records are accessed only by current government-authorized personnel whose official duties require access to the records. Electronic authorization and authentication of users is required at all points before any system information can be accessed. Communications are encrypted where required and other safeguards are in place to monitor and audit access, and to detect intrusions. System backup is maintained separately.

RECORD ACCESS PROCEDURES:

As specified below, records in this system have been exempted from certain notification, access, and amendment procedures. A request for access shall be made in writing with the envelope and letter clearly marked ''Privacy Act Request.'' Requesters shall provide their full name and complete address. The requester must sign the request and have it verified by a notary public. Alternately, the request may be submitted under 28 U.S.C. 1746, certifying the requester's identity and understanding that obtaining a record under false pretenses constitutes a criminal offense. Requests for access to information must be addressed to the Director, Information Management Office, Chief Operating Officer, Office of the Director of National Intelligence, Washington, DC 20511. Regulations governing access to one's records or for appealing an initial determination concerning access to records are contained in the ODNI regulation implementing the Privacy Act, 32 CFR part 1701 (73 FR 16531).

CONTESTING RECORD PROCEDURES:

As specified below, records in this system are exempt from certain notification, access, and amendment procedures. Individuals seeking to correct or amend non-exempt records should address their requests to ODNI at the address and according to the requirements set forth above under the heading ''Record Access Procedures.'' Regulations governing access to and amendment of one's records or for appealing an initial determination concerning access or amendment of records are contained in the ODNI regulation implementing the Privacy Act, 32 CFR part 1701 (73 FR 16531).

NOTIFICATION PROCEDURES:

As specified below, records in this system are exempt from certain notification, access, and amendment procedures. Individuals seeking to learn whether this system contains non-exempt information about them should address inquiries to ODNI at the address and according to the requirements set forth above under the heading ''Record Access Procedures.''

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

The Privacy Act authorizes ODNI to exempt records contained in this system of records from the requirements of subsections (c)(3), (d)(1), (d)(2), (d)(3), (d)(4), (e)(1), (e)(4)(G), (H), (I), and (f) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(1), (k)(2) and (k)(5). In addition, pursuant to published rule, ODNI may derivatively exempt records from other agencies in this system from the requirements of the subsections listed above, as well as subsections (c)(4), (e)(2), (e)(3), (e)(5), (e)(8), (e)(12), and (g) of the Privacy Act consistent with any exemptions claimed under 5

U.S.C. 552a(j) or (k) by the originator of the record, provided the reason for the exemption remains valid and necessary.

HISTORY:

This is a revision to an existing ODNI/NCSC CE system of records, Continuous Evaluation Records (ODNI/NCSC–003), 83 FR 61395 (Nov. 29, 2018).

In accordance with 5 U.S.C. 552(r), ODNI has provided a report of this revision to the Office of Management and Budget and to Congress.

Gregory M. Koch,

Director, Information Management Office, Chief Operating Officer, Office of the Director of National Intelligence.

[FR Doc. 2021–24267 Filed 11–4–21; 8:45 am]

BILLING CODE 9500–01–P–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by December 6, 2021. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314 or *ACApermits@nsf.gov.*

FOR FURTHER INFORMATION CONTACT: Polly Penhale, ACA Permit Officer, at the above address, 703–292–8030.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 670), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Application Details

Permit Application: 2022–021

1. *Applicant* Henry Wulff, Altas Ocean Voyages, 1 E Broward Blvd., Suite 800, Fort Lauderdale, FL, 33301.

Activity for Which Permit is Requested: Waste Management. The applicant seeks an Antarctic Conservation Act permit for waste management activities associated with the use of remotely piloted aircrafts (RPAs) in Antarctica. RPAs will be flown by experienced, pre-approved pilots for educational, commercial, or marketing purposes only. RPAs will only be flown in fair-weather conditions with wind speeds less than 7m/s. Aircrafts will not be flown over any concentrations of wildlife, or any Antarctic Specially Protected or Specially Managed Areas or any Historic Sites and Monuments without authorization. Operators and observers will maintain visual line of sight with the aircraft during all flight operations, and measures will be in place to prevent loss of aircraft during operations. The applicant seeks a waste management permit to cover any accidental release that may result from the use of RPAs.

Location: Antarctic Peninsula Region.

Dates of Permitted Activities: December 1, 2021–March 31, 2022.

Permit Application: 2022–022

2. *Applicant:* Deirdre Dirkman, Vantage Travel, 90 Canal St., Boston, MA 02114.

Activity for Which Permit is Requested: Waste Management. The applicant seeks an Antarctic Conservation Act permit for waste management activities associated with the use of remotely piloted aircrafts (RPAs) in Antarctica. Flights of RPAs will be limited to commercial, educational, and marketing use only. Aircraft are only to be flown by experienced, pre-approved pilots in fair weather conditions. RPAs will not be flown over any concentrations of wildlife, Antarctic Specially Protected or Specially Managed Areas or any Antarctic Historic Sites and Monuments without appropriate authorization. Operators will always maintain visual line of site with aircraft during flight to monitor activities and prevent loss of aircraft. Observers will assist in monitoring and observe for any wildlife or potential hazards. The applicant seeks a permit to cover any accidental release that may result from RPA use.

Location: Antarctic Peninsula Region.

Dates of Permitted Activities: December 1, 2021–March 31, 2022.

Permit Application: 2022–023

3. *Applicant:* Tom Russell, Swan Hellenic Antarctic, 1800 SE 10th Ave., #240, Fort Lauderdale, FL 33316.

Activity for Which Permit is Requested: Waste Management. The applicant seeks an Antarctic Conservation Permit for waste management activities associated with use of remotely piloted aircrafts (RPAs) in Antarctica. Aircrafts will be launched from land or by boat and will be used for commercial, marketing, or educational purposes only. RPAs will not be flown over any concentrations of wildlife, Antarctic Specially Protected or Specially Managed Areas or Historic Sites and Monuments without appropriate authorization. Aircraft are only to be flown by experienced, pre-approved pilots in fair weather conditions and in the presence of an observer, who will observe the flight area for potential hazards. Measures are in place to prevent loss of the aircraft. The applicant seeks a waste management permit to cover any accidental releases that may result from RPA use.

Location: Antarctic Peninsula Region.

Dates of Permitted Activities: December 1, 2021–March 31, 2021.

Permit Application: 2022–024

4. *Applicant:* Michael Hjorth, Albatros Expeditions, 4770 Biscayne Blvd., PHR, Miami, FL 33137.

Activity for Which Permit is Requested: Waste Management. The applicant seeks an Antarctic Conservation Act permit for waste management activities associated with the use of Remotely piloted aircrafts (RPAs) and all-terrain vehicles (ATVs) in Antarctica. RPAs will be flown by experienced, pre-approved pilots for educational, commercial, or marketing purposes. Aircrafts will not be flown over any concentrations of wildlife, or any Antarctic Specially Protected or Specially Managed Areas or Historic Sites and Monuments without appropriate authorization. Operators will maintain visual line of sight with the aircraft during all flight operations, and measures will be in place to prevent loss of aircraft during operations. Observers will be present to observe for any wildlife or other potential hazards. ATVs will be used to support onshore activities and will be refueled once daily. Refueling of ATVs will be done by experienced staff and precautions will be taken to prevent any accidental release of fuel. Supplies will be on hand to assist in cleanup of any fuel spilled during operations. The applicant seeks a waste management permit to cover any accidental release that may result from the use of RPAs or ATVs.

Location: Antarctic Peninsula Region.

Dates of Permitted Activities: December 1, 2021–March 31, 2022.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2021–24278 Filed 11–4–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of the Networking and Information Technology Research and Development Program 30th Anniversary Commemoration

AGENCY: Networking and Information Technology Research and Development (NITRD) Program National Coordination Office (NCO), National Science Foundation.

ACTION: Notice of meeting.

SUMMARY: The NITRD Subcommittee will hold a virtual public meeting to mark the 30th anniversary of the signing of the High-Performance Computing (HPC) Act of 1991 and the launching of the High-Performance Computing and Communications Program, now known as the NITRD Program. One of the key parts of this legislation was to establish an effective mechanism to coordinate HPC, networking, and information technology (IT) research and development (R&D) undertaken by the agencies of the Federal Government. The legislation also expanded Federal funding support for HPC and IT R&D to ensure continued technological leadership in these areas by the United States. The Act aimed to provide U.S. researchers and educators, as well as government and the public, with the advanced computing and information resources they needed for achievement of personal, business, and public goals. The NITRD mission has expanded over the last three decades as the capabilities of advanced computing, networking, and IT technologies increased dramatically. Join us as we recognize and celebrate the origins and expansion of America's IT innovation highway.

DATES: December 2, 2021.

ADDRESSES: The meeting will be held virtually through Zoom, 12 Noon (EST).

Instructions: Registration is required. You will be asked to provide your name, email address, and affiliation. The meeting link will be available on *https://www.nitrd.gov/nitrd-30th-anniversary-commemoration/.*

FOR FURTHER INFORMATION CONTACT: Diana Weber at *nco@nitrd.gov* or call 202–459–9684. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background/Objectives/Overview: The NITRD Program is the Nation's primary source of federally funded IT R&D, critical to promoting and protecting American leadership in science and technology (S&T) innovation. The NITRD Program focuses its work on addressing strategic IT R&D imperatives that lead to cutting-edge computing, networking, and information technologies that support U.S. national security, economic competitiveness, and individual health and well-being. One of the key parts of the 1991 legislation was to establish a mechanism to lead the coordination and planning of multiagency and multisector HPC R&D to maximize the effectiveness of the Federal Government's R&D investments and the transition of discoveries to societal benefit. This vital mission has expanded over the years to include coordination of Federal agencies' R&D broadly across critical computing- and IT-related topics in advanced wireless technologies, artificial intelligence, big data, cybersecurity, health IT, networked physical systems, privacy protection, robotics, and software productivity and sustainability. Through NITRD, Federal agencies exchange information; collaborate on research activities such as testbeds, workshops, strategic planning, and cooperative solicitations; and focus their R&D resources on common goals of making new discoveries and/or developing new technology solutions to address our Nation's most critical priorities. As an example, NITRD-linked HPC and IT R&D underpinned U.S. leadership in fighting COVID–19, not only to speed discovery of therapeutics and vaccines but also to support Americans in conducting their personal relationships, education, healthcare, and businesses remotely wherever possible. *The increased national commitment to IT R&D has been reflected in the growth in combined investment requests by NITRD's Federal member agencies from less than $5 million in 1991 to nearly $6.5 billion requested for FY2021. For more information about the NITRD Program, please visit our website: https://www.nitrd.gov/about/.*

Submitted by the National Science Foundation in support of the Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO) on November 2, 2021.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2021–24290 Filed 11–4–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Social, Behavioral and Economic Sciences Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Social, Behavioral and Economic Sciences (#1171).

Date and Time: December 2–3, 2021; 12:00 p.m.–5:00 p.m. (ET)

Place: NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314. Virtual AC Meeting via Zoom. Advance registration is required: SBE Fall 2021 Advisory Committee Meeting Registration Link.

Type of Meeting: Open.

Contact Person: Dr. Deborah Olster, Office of the Assistant Director, Directorate for Social, Behavioral and Economic Sciences; National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone: (703) 292–8700.

Summary of Minutes: Will be available on the SBE advisory committee website at: *https://www.nsf.gov/sbe/advisory.jsp.*

Purpose of Meeting: To provide advice and recommendations to the National Science Foundation on major goals and policies pertaining to Social, Behavioral and Economic Sciences Directorate (SBE) programs and activities.

Agenda Items

- Welcome, Introductions, Approval of Previous Advisory Committee (AC) Meeting Summary, Preview of Agenda
- Directorate for Social, Behavioral and Economic Sciences (SBE) Update
- Division of Social and Economic Sciences Committee of Visitors
- NSF Activities Related to Climate Change
- Interagency Subcommittee on Open Science
- America's Data Hub
- Translation, Innovation and Partnerships
- New AC Member Presentation
- National Institutes of Health/Centers for Disease Control and Prevention Activities
- COVID–19 Research Update
- Meeting with NSF Leadership
- Directorates for Social, Behavioral and Economic Sciences and for Computer and Information Sciences and Engineering (CISE): Collaborative Opportunities
- Research Infrastructure in the Social, Behavioral and Economic Sciences
- SBE AC Subcommittees
- Wrap-up, Assignments and Closing Remarks

Dated: November 1, 2021.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2021–24180 Filed 11–4–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permits issued.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Polly Penhale, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–8030; email: *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: On September 30, 2021, the National Science Foundation published a notice in the **Federal Register** of permit applications received. The permits were issued on November 2, 2021, to:

	Permit No.
1. John Durban, Ph.D	2022–010
2. John Durban, Ph.D	2022–011

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2021–24277 Filed 11–4–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL TRANSPORTATION SAFETY BOARD

SES Performance Review Board

AGENCY: National Transportation Safety Board.

ACTION: Notice.

SUMMARY: Notice is hereby given of the appointment of members of the National Transportation Safety Board, Performance Review Board (PRB).

FOR FURTHER INFORMATION CONTACT: Emily T. Carroll, Chief, Human Resources Division, Office of Administration, National Transportation Safety Board, 490 L'Enfant Plaza SW, Washington, DC 20594–0001, (202) 314–6233.

SUPPLEMENTARY INFORMATION: Section 4314(c)(1) through (5) of Title 5, United States Code requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more SES Performance Review Boards (PRB). The board reviews and evaluates the initial appraisal of a senior executive's performance by the supervisor and considers recommendations to the appointing authority regarding the performance of the senior executive.

The following have been designated as members of the 2021 Performance Review Board of the National Transportation Safety Board (NTSB):

Ms. Dolline Hatchett, Director, Office of Safety Recommendations and Communications, National Transportation Safety Board, PRB Chair

Mr. Robert Molloy, Director, Office of Highway Safety, National Transportation Safety Board

Mr. Timothy LeBaron, Acting Director, Office of Aviation Safety, National Transportation Safety Board

Mr. Jerold Gidner, Director, Bureau of Trust Funds Administration, U.S. Department of Interior

Ms. Katherine Herrera, Deputy Technical Director, Defense Nuclear Facilities Safety Board

Mr. James Ritter, Director, Office of Research and Engineering, National Transportation Safety Board (alternate)

Dated: November 2, 2021.

Candi R. Bing,

Federal Register Liaison.

[FR Doc. 2021–24292 Filed 11–4–21; 8:45 am]

BILLING CODE P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0186]

Privacy Act of 1974; Systems of Records

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of new system of records.

SUMMARY: Pursuant to the Privacy Act of 1974 and Office of Management and Budget (OMB) Circular No. A–108, notice is hereby given that the U.S. Nuclear Regulatory Commission (NRC) proposes to develop a new system of records notice titled, ''Health Emergency Records,'' NRC 46. NRC proposes to establish this system of records to protect the NRC's workforce and respond to the Coronavirus Disease 2019 (COVID–19), a declared public health emergency, and other high consequence public health threats.

DATES: Submit comments on this new system of records by December 6, 2021. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date. This proposed action will be effective on the day following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal Rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0186. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

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

FOR FURTHER INFORMATION CONTACT: Sally Hardy, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–5607; email: *Sally.Hardy@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0186 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0186.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search select, ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email *pdr.resource@nrc.gov.*
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2021–0186 in the

subject line of your comment submission.

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

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

II. Background

Pursuant to the Privacy Act of 1974 and OMB Circular No. A–108, ''Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act,'' notice is hereby given that the NRC proposes to establish this system of records notice.

The proposed new system requires an advance period for public comment.

A report on this new system has been sent to OMB, the Committee on Homeland Security and Governmental Affairs of U.S. Senate, and the Committee on Oversight and Reform of the U.S. House of Representatives, as required by the Privacy Act.

If changes are made based on the NRC's review of comments received, the NRC will publish a subsequent notice.

SUPPLEMENTARY INFORMATION: The text of the report is attached.

Dated: November 2, 2021.

For the Nuclear Regulatory Commission.

Scott C. Flanders,

Senior Agency Official for Privacy, Office of the Chief Information Officer.

Attachment—Nuclear Regulatory Commission Privacy Act Systems of Records

NRC Systems of Records

46. Health Emergency Records—NRC

This system of record is maintained by the NRC and contains personal information about individuals from which information is retrieved by an individual's name or identifier.

The notice for this system of records states the name and location of the record system, the authority for and manner of its operation, the categories of individuals that it covers, the types of records that it contains, the sources of information in those records, and the routine uses. This notice also includes the business address of the NRC official who will inform interested persons of the procedures whereby they may gain access to and request amendment of records pertaining to them.

The Privacy Act provides certain safeguards for an individual against an invasion of personal privacy by requiring Federal agencies to protect records contained in an agency system of records from unauthorized disclosure and to ensure that information is current and accurate for its intended use and that adequate safeguards are provided to prevent misuse of such information.

SYSTEM NAME AND NUMBER:

Health Emergency Records—NRC 46.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Headquarters, 11555 Rockville Pike, Rockville, Maryland. Records may be maintained at all locations at which the NRC, or contractors on behalf of the NRC, operate or at which NRC operations are supported.

SYSTEM MANAGER(S):

Chief Human Capital Officer, Office of the Chief Human Capital Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Workforce safety Federal requirements, including the Occupational Safety and Health Act of 1970; Executive Order 12196, ''Occupational safety and health programs for Federal employees;'' 5 U.S.C. 7902, ''Safety programs;'' Federal laws related to a specific public health emergency or high-consequence public health threats, including, Executive Order 13991, ''Protecting the Federal Workforce and Requiring Mask-Wearing,'' Executive Order 13994, ''Ensuring a Data-Driven Response to COVID–19 and Future High-Consequence Public Health Threats,'' Executive Order 14042, ''Ensuring Adequate COVID Safety Protocols for Federal Contractors,'' and Executive Order 14043, ''Requiring Coronavirus Disease 2019 Vaccination for Federal Employees,'' Federal laws that authorize the NRC to create and maintain Federal records of agency activities, including 44 U.S.C. 3101; the Religious Freedom Restoration Act of 1933, 42 U.S.C. Chapter 21B; Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000e; and the Rehabilitation Act of 1973, as amended, 29 U.S.C. 701 *et seq.*

PURPOSE(S) OF THE SYSTEM:

This system is to maintain records necessary and relevant to NRC activities responding to and mitigating high-consequence public health threats, including, but not limited to: COVID–19 or diseases and illnesses relating to a public health emergency, pandemic, or other high-consequence public health threat. The President's September 9, 2021, Executive Order 14043, requires all Federal workers to be vaccinated, except in limited circumstances as required by law. Accordingly, this this system of records is also designed to collect records related to vaccination status, including requests for an exception to the vaccination requirement. Such records may include, but are not limited to, those records needed to understand the impact of an illness or disease on the NRC workforce, to assist the NRC in protecting its workforce from a declared public health emergency, pandemic, or other high-consequence public health threat, as well as those records submitted by NRC personnel, or the lawful representative of such personnel, requesting an exception to the vaccination requirement contained in Executive Order 14043, or other applicable law.

Among other things, the NRC may use the information collected to facilitate the provision of vaccines to NRC personnel, including employees, interns, and contractors; to inform individuals who may have been in proximity of a person possibly infected with a disease, illness, or other high-consequence public health threat at or on buildings, grounds, and properties that are owned, leased, or used by the NRC; to confirm which personnel have received vaccinations to prevent such disease or illness to spread throughout the NRC's workforce; to consider requests for an exception to the COVID–19 vaccination requirement; to respond to inquiries regarding such vaccinations for purposes related to official agency travel, access to licensee facilities, NRC site access, or implementation/lifting of access restrictions; or to determine and report the aggregate number of vaccinated NRC staff, or the number of staff that received a legal exception to the vaccine requirement.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NRC's personnel, including employees, interns, and contractors.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records maintained in this system may include:

A. Full name, NRC employee ID number; telephone number, worksite, email address, supervisor's name, address and contact information and/or the contractor's supervisor/contracting officer representative name, address and contact information.

B. Date(s) and circumstances of the individual's suspected or actual exposure to disease or illness including symptoms, as well as locations within the NRC workplace where the individual may have contracted or been exposed to the disease or illness.

C. Other information of the individual directly related to the disease or illness (*e.g.,* testing results/information, symptoms, treatments, and source of exposure).

D. Appointment scheduling information, including the date, time, and location of a scheduled appointment.

E. Medical screening information, including the individual's name, date of birth, age, category of employment, current medical status, vaccination history, and any relevant medical history.

F. Vaccination records, including the date, type, and dose of vaccine administered to the individual.

G. Requests for an exception to the COVID–19 vaccination requirement, including, but not limited to, the employee's name and relevant information related to the request.

RECORD SOURCE CATEGORIES:

Records may be obtained from NRC personnel, including employees, contractors, and interns, who may provide relevant information on a suspected or confirmed disease or illness, or the prevention of such disease or illness, which is the subject of a declared public health emergency, or information related to a request for an exception from the COVID–19 vaccination requirement. Information may also be sourced from personnel at medical facilities, or from existing systems of records, including but not limited to NRC–43, ''Employee Health Center Records,'' (84 FR 71536; December 27, 2019) or OPM/GOVT–10, ''Employee Medical File System Records,'' (75 FR 35099; June 21, 2010), and modified on November 30, 2015 (80 FR 74815).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the persons or entities mentioned herein if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

A. To appropriate medical facilities, or Federal, State, local, Tribal, territorial or foreign government agencies, to the extent permitted by law, for the purpose of protecting the vital interests of individual(s), including to assist the United States Government in responding to or mitigating high-consequence public health threats, or diseases and illnesses relating to a public health emergency.

B. To determine eligibility for access to NRC buildings, NRC licensee facilities or sites, or other Federal facilities.

C. To provide licensees information needed for unescorted access or access to the licensee's facility(s).

D. Where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant records may be referred to the appropriate Federal, State, local, territorial, Tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law.

E. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body, when the NRC determines that the records are arguably relevant to its proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

F. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal Government, when necessary to accomplish an NRC function related to this system of records.

G. A record on an employee or contractor from this system of records may be disclosed as a routine use to a Federal, State, local, territorial, Tribal, or foreign agency requesting a record that is relevant and necessary to its decision on a matter of hiring or retaining an employee, issuing a security clearance, reporting an investigation of that individual, letting a contract, or issuing a license, grant, or other benefit.

H. A record on an employee or contractor from this system of records may be disclosed as a routine use to a Congressional office in response to an inquiry from the Congressional office made at the request of that individual.

I. To the National Archives and Records Administration for purposes of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

J. To appropriate agencies, entities, and persons when (1) the NRC suspects or has confirmed that there has been a breach of the system of records. (2) the NRC has determined that as a result of the suspected or confirmed breach there is a risk of harm to an individual(s), the NRC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the NRC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

K. To another Federal agency or Federal entity, when the NRC determines that information from this system of records is necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach, or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

L. To any agency, organization, or individual for the purpose of performing authorized audit or oversight operations of the NRC and meeting related reporting requirements.

M. To such recipients and under such circumstances and procedures as are mandated by Federal statute or treaty.

N. A record from this system of records may be disclosed as a routine use to NRC-paid experts or consultants, and those under contract with the NRC on a ''need-to-know'' basis for purpose within the scope of the pertinent NRC task. This access will be granted to an NRC contractor or employee of such contractor by a system manager only after satisfactory justification has been provided to the system manager.

O. To a Federal agency employee, expert, consultant, or contractor in performing a Federal duty for purposes of authorizing, arranging, and/or claiming reimbursement for official travel, including, but not limited to, traveler profile information.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

All records in this system of records are maintained and in compliance with applicable executive orders, statutes, and agency implementing recommendations. Electronic records are stored in databases and/or on hard disks, removable storage devices, or other electronic media. Paper records are maintained in a secure, access controlled room, with access limited to authorized personnel.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records will be retrieved by any of the categories of records, including name, location, date of vaccination, or work status.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

To the extent applicable, to ensure compliance with Americans with Disabilities Act, the Rehabilitation Act, and the Genetic Information Nondiscrimination Act of 2008, medical information must be ''maintained on separate forms and in separate medical files and be treated as a confidential medical record.'' 42 U.S.C. 12112(d)(3)(B); 42 U.S.C. sec 2000ff–5(a); 29 CFR 1630.14(b)(1), (c)(1),(d)(4)(i); and 29 CFR 1635.9(a). This means that medical information and documents must be stored separately from other personnel records. As such, the NRC must keep medical records for at least 1 year from creation date. 29 CFR 1602.14. Further, records compiled under this system of record notices will be maintained in accordance with the National Archives and Records Administration General Records Schedule 2.7 Employee Health and Safety Records, Items 010, 070, or 080 to the extent applicable.

GRS 2.7 item 010 (DAA–GRS–2017–0010–0001)—Clinic scheduling records. Temporary. Destroy when 3 years old, but longer retention is authorized if needed for business use.

GRS 2.7 item 070 (DAA–GRS–2017–0010–0012)—Non-occupational individual case files. Temporary. Destroy 10 years after the most recent encounter, but longer retention is authorized if needed for business use.

GRS 2.7 item 080 (DAA–GRS–2017–0010–0013)—Non-occupational health and wellness program records. Temporary. Destroy 3 years after the project/activity/or transaction is completed or superseded, but longer retention is authorized if needed for business use.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The NRC safeguards records in this system according to applicable rules and polices, including all applicable NRC automated systems security and access policies. The NRC has imposed controls to minimize the risk of compromising the information that is being stored. Users of individual computers can only gain access to the data by valid user identification and password. Paper records are maintained in a secure, access- controlled room, with access limited to authorized personnel.

RECORDS ACCESS PROCEDURES:

Same as ''Notification procedures.''

CONTESTING RECORD PROCEDURES:

Same as ''Notification procedures.''

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act Officer or Privacy Act Officer, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

HISTORY:

None.

Addendum I—List of U.S. Nuclear Regulatory Commission Locations

Part 1—NRC Headquarters Offices

1. One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

2. Two White Flint North, 11545 Rockville Pike, Rockville, Maryland.

Part 2—NRC Regional Offices

1. NRC Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, Pennsylvania.

2. NRC Region II, Marquis One Tower, 245 Peachtree Center Avenue NE, Suite 1200, Atlanta, Georgia.

3. NRC Region III, 2443 Warrenville Road, Suite 210, Lisle, Illinois.

4. NRC Region IV, 1600 East Lamar Boulevard, Arlington, Texas.

5. NRC Technical Training Center, Osborne Office Center, 5746 Marlin Road, Suite 200, Chattanooga, Tennessee.

[FR Doc. 2021–24283 Filed 11–4–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of November 8, 15, 22, 29, December 6, 13, 2021.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

MATTERS TO BE CONSIDERED:

Week of November 8, 2021

There are no meetings scheduled for the week of November 8, 2021.

Week of November 15, 2021—Tentative

There are no meetings scheduled for the week of November 15, 2021.

Week of November 22, 2021—Tentative

There are no meetings scheduled for the week of November 22, 2021.

Week of November 29, 2021—Tentative

There are no meetings scheduled for the week of November 29, 2021.

Week of December 6, 2021—Tentative

Tuesday, December 7, 2021

10:00 a.m. Briefing on Equal Employment Opportunity, Affirmative Employment, and Small Business (Public Meeting); (Contact: Larniece McKoy Moore: 301–415–1942)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

Thursday, December 9, 2021

9:00 a.m. Briefing on 10 CFR part 53 Licensing and Regulations of Advanced Nuclear Reactors (Public Meeting); (Contact: Caty Nolan: 301–415–1535)

Additional Information: Due to COVID–19, there will be no physical public attendance.

The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

Week of December 13, 2021—Tentative

There are no meetings scheduled for the week of December 13, 2021.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.* The schedule for

Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Tyesha.Bush@nrc.gov* or *Betty.Thweatt@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: November 3, 2021.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2021–24406 Filed 11–3–21; 4:15 pm]

BILLING CODE 7590–01–P

SCIENCE AND TECHNOLOGY POLICY OFFICE

Orbital Debris Research and Development Plan

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Notice of Request for Comment (RFC).

SUMMARY: On behalf of the National Science and Technology Council (NSTC), Committee on Homeland and National Security, Subcommittee on Space Weather Security and Hazards, Interagency Working Group on Orbital Debris Research and Development, OSTP requests input from all interested parties on the Orbital Debris Research and Development (R&D) Plan, which will inform the Orbital Debris Research and Development Interagency Working Group's activity for building out an implementation plan.

DATES: Responses are due by December 31, 2021.

ADDRESSES: Interested individuals and organizations should submit comments electronically to Ezinne Uzo-Okoro at *OrbitalDebris@ostp.eop.gov.* Further information may be received by calling 202–456–4444.

Instructions: Response to this RFC is voluntary. Respondents need not reply to all questions listed. Each individual or institution is requested to submit only one response. OSTP and/or NSTC may post responses to this RFC, without change, on a Federal website. OSTP, therefore, requests that no business proprietary information, copyrighted information, or personally identifiable information be submitted in response to this RFC. Please note that the United States Government will not pay for response preparation, or for the use of any information contained in the response.

SUPPLEMENTARY INFORMATION: The Orbital Debris Interagency Working Group has commenced the development of an implementation plan to be released in 2022. Pursuant to 42 U.S.C. 6622, OSTP is soliciting public input through this RFC to obtain recommendations from a wide range of stakeholders, including representatives from diverse industries, academia, other relevant organizations and institutions, and the general public. The public input provided in response to this RFC will inform OSTP and NSTC as they work with Federal agencies and other stakeholders to develop an Orbital Debris implementation plan. This implementation plan is building off the R&D plan published in January 2021.

Implementing this plan will close critical gaps in the knowledge and capabilities needed to meet current and growing challenges of orbital debris risk management. The R&D Plan organizes the orbital debris challenges and research topical areas into three main areas of orbital debris research and development: limiting debris generation by design, tracking and characterizing debris, and remediating or repurposing debris. OSTP seeks public input from the R&D community on what R&D areas are priorities for government-sponsored initiatives/coordination, the roles of academia, nonprofit, and industry actors in addressing these actions, and potential avenues for coordination between actors across public and private sectors.

Questions To Inform Development of the Plan

OSTP seeks responses to the following questions to improve government coordination and to provide long-term guidance for Federal programs and activities in support of the United States Orbital Debris Research & Development implementation plan.

(1) The extent to which progress in the R&D topical areas identified in the Orbital Debris R&D Plan will address the orbital debris challenges. What, if any, R&D areas are missing?

(2) Among the topic areas listed in the R&D Plan, what are the highest priority R&D areas (up to five) for making progress in addressing the challenges posed by orbital debris to the space environment?

(3) What near-term actions can be taken by the Federal government to make progress towards high priority R&D areas? How would these specific actions address the orbital debris challenges in the near term?

(4) What R&D activities would be most valuable in the long-term or would be the most transformative to addressing orbital debris challenges?

(5) What are the opportunities to partner with entities outside the Federal government, nationally and internationally? What are the viable and potentially innovative mechanisms to partner most effectively?

Dated: November 1, 2021.

Stacy Murphy,

Operations Manager.

[FR Doc. 2021–24125 Filed 11–4–21; 8:45 am]

BILLING CODE 3271–F1–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–335, OMB Control No. 3235–0381]

Proposed Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street, NE, Washington, DC 20549–2736

Extension:
Form 40–F

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form 40–F (17 CFR 249.240f) is used by certain Canadian issuers to register a class of securities under Section 12 of the Securities Exchange Act of 1934

(''Exchange Act'') (15 U.S.C. 78*l*) or as an annual report pursuant to Section 13(a) or 15 (d) of the Exchange Act (15 U.S.C. 78m(a) or 78o(d)). The information required in the Form 40–F is used by investors in making investment decisions with respect to the securities of such Canadian companies. We estimate that Form 40–F takes approximately 431.42 hours per response and is filed by approximately 132 respondents. We estimate that 25% of the 429.93 hours per response (107.855 hours) is prepared by the issuer for a total reporting burden of 14,237 (107.855 hours per response × 132 responses).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

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 control number.

Please direct your written comment to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24138 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission Small Business Capital Formation Advisory Committee will hold a public meeting on Tuesday, November 16, 2021, via videoconference.

PLACE: The meeting will begin at 10:00 a.m. (ET) and will be open to the public. The meeting will be conducted by remote means (videoconference) and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549. Members of the public may watch the webcast of the meeting on the Commission's website at *www.sec.gov.*

STATUS: On October 22, 2021, the Commission published notice of the Committee meeting (Release No. 33–11002), indicating that the meeting is open to the public and inviting the public to submit written comments to the Committee. This Sunshine Act notice is being issued because a majority of the Commission may attend the meeting.

MATTERS TO BE CONSIDERED: The agenda for the meeting includes matters relating to rules and regulations affecting small and emerging businesses and their investors under the federal securities laws.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

(Authority: 5 U.S.C. 552b)

Dated: November 3, 2021.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2021–24345 Filed 11–3–21; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–560, OMB Control No. 3235–0622]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Interagency Statement on Sound Practices

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in the Interagency Statement on Sound Practices Concerning Elevated Risk Complex Structured Finance Activities (''Statement'') under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act'') and the Investment Advisers Act of 1940 (15 U.S.C. 80b *et seq.*) (''Advisers Act'').

The Statement was issued by the Commission, together with the Office of the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, and the Office of Thrift Supervision (together, the ''Agencies''), in May 2006. The Statement describes the types of internal controls and risk management procedures that the Agencies believe are particularly effective in assisting financial institutions to identify and address the reputational, legal, and other risks associated with elevated risk complex structured finance transactions.

The primary purpose of the Statement is to ensure that these transactions receive enhanced scrutiny by the institution and to ensure that the institution does not participate in illegal or inappropriate transactions.

The Commission estimates that approximately 5 registered broker-dealers or investment advisers will spend an average of approximately 25 hours per year complying with the Statement. Thus, the total time burden is estimated to be approximately 125 hours per year.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24132 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34414; 812–15200]

AFA Multi-Manager Credit Fund and Alternative Fund Advisors, LLC

November 2, 2021.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(a)(2), 18(c) and 18(i) of the Act, under sections 6(c) and 23(c) of the Act for an exemption from rule 23c–3 under the Act, and for an order pursuant to section 17(d) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed-end management investment companies to issue multiple classes of shares with varying sales loads and asset-based service and/or distribution fees and to impose early withdrawal charges (''EWCs'').

APPLICANTS: AFA Multi-Manager Credit Fund (the ''Initial Fund'') and Alternative Fund Advisors, LLC (the ''Adviser'' and together with the Initial Fund, the ''Applicants'').

FILING DATES: The application was filed on February 5, 2021, and amended on April 30, 2021 and July 20, 2021.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving Applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on November 29, 2021 and should be accompanied by proof of service on the Applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing to the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Joshua B. Deringer, by email to *joshua.deringer@faegredrinker.com.*

FOR FURTHER INFORMATION CONTACT: Steven B. Levine, Senior Counsel, or Nadya Roytblat, Assistant Chief Counsel, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Initial Fund is a Delaware statutory trust that is registered under the Act as a closed-end management investment company and operated as an interval fund pursuant to rule 23c–3 under the Act. The primary investment objective of the Initial Fund is to provide a high level of current income, with capital appreciation as a secondary objective. The Initial Fund pursues its investment objective primarily by investing, either directly or indirectly, in a range of private and public credit securities and other credit-related investments.

2. The Adviser is a Delaware limited liability company and is an investment adviser registered with the Commission under the Investment Advisers Act of 1940. The Adviser serves as investment adviser to the Initial Fund.

3. Applicants seek an order to permit the Funds (as defined below) to issue multiple classes of interests (''Shares'') [1] with varying sales loads and asset-based service and/or distribution fees and to impose EWCs.

4. Applicants request that the order also apply to any continuously-offered registered closed-end management investment company that has been previously organized or that may be organized in the future for which the Adviser or any entity controlling, controlled by, or under common control with the Adviser, or any successor in interest to any such entity,[2] acts as investment adviser and that operates as an interval fund pursuant to rule 23c–3 under the Act or provides periodic liquidity with respect to its shares pursuant to rule 13e–4 under the Securities Exchange Act of 1934, as amended (the ''Exchange Act'') (each, a ''Future Fund'' and together with the Initial Fund, the ''Funds'').[3]

5. The Initial Fund is currently offering its common shares of beneficial interest (''Initial Class Shares'') on a continuous basis. Applicants state that additional offerings by any Fund relying on the order may be on a private placement or public offering basis. Shares of the Funds will not be listed on any securities exchange, nor quoted on any quotation medium, and the Funds do not expect there to be a secondary trading market for their Shares.

6. If the requested relief is granted, the Initial Fund intends to continuously offer at least one additional class of Shares (''New Class Shares''). Each of the Initial Class Shares and the New Class Shares will have its own fee and expense structure. Because of the different distribution and/or service fees, services, and any other class expenses that may be attributable to each class of Shares, the net income attributable to, and the dividends payable on, each class of Shares may differ from each other.

7. Applicants state that, from time to time, the Initial Fund may create additional classes of Shares, the terms of which may differ from its Initial Class Shares and New Class Shares pursuant to and in compliance with rule 18f–3 under the Act.

8. Applicants state that Shares of a Fund may be subject to a repurchase fee at a rate not to exceed 2% of the aggregate net asset value of a shareholder's Shares repurchased by a Fund (an ''Early Repurchase Fee'') if the interval between the date of purchase of the Shares and the valuation date with respect to the repurchase of those Shares is less than one year. Any Early Repurchase Fee imposed by a Fund will apply to all classes of Shares of the Fund, consistent with section 18 of the Act and rule 18f–3 thereunder. Further, Applicants represent that, to the extent a Fund determines to waive, impose scheduled variations of, or eliminate any Early Repurchase Fee, it will do so consistently with the requirements of rule 22d–1 under the Act as if the Early Repurchase Fee were a CDSL (defined below) and as if the Fund were an open-end investment company and the Fund's waiver of, scheduled variation in, or elimination of, any such Early Repurchase Fee will apply uniformly to all shareholders of the Fund regardless of class.

[1] As used in the application, ''Shares'' includes any other equivalent designation of a proportionate ownership interest of the Initial Fund (or any other registered closed-end management investment company relying on the requested order).

[2] A successor in interest is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[3] Applicants represent that any of the Funds relying on this relief in the future will do so in a compliance with the terms and conditions of the application. Applicants further represent that each entity presently intending to rely on the requested relief is listed as an Applicant.

9. Applicants state that the Initial Fund has adopted a fundamental policy to repurchase a specified percentage of its Shares (no less than 5% and no more than 25%) at net asset value on a quarterly basis. Such repurchase offers will be conducted pursuant to rule 23c–3 under the Act. Each of the other Funds will likewise adopt fundamental investment policies and make periodic repurchase offers to its shareholders in compliance with rule 23c–3 or will provide periodic liquidity with respect to its shares pursuant to rule 13e–4 under the Exchange Act.[4] Any repurchase offers made by the Funds will be made to all holders of Shares of each such Fund.

10. Applicants represent that any asset-based service and/or distribution fees for each class of Shares of the Funds will comply with the provisions of FINRA Rule 2341(d) (formerly NASD rule 2380(d)) (the ''FINRA Sales Charge Rule'').[5] Applicants also represent that each Fund will include in its prospectus disclosure of the fees, expenses and other characteristics of each class of Shares offered for sale by the prospectus, as is required for open-end multi-class funds under Form N–1A.[6] As is required for open-end funds, each Fund will disclose fund expenses borne by shareholders during the reporting period in shareholder reports, and describe in its prospectus any arrangements that result in breakpoints in, or elimination of, sales loads.[7] In addition, applicants will comply with applicable enhanced fee disclosure requirements for fund of funds including registered funds of hedge funds.[8]

11. Each Fund will comply with any requirements that the Commission or FINRA may adopt regarding disclosure at the point of sale and in transaction confirmations about the costs and conflicts of interest arising out of the distribution of open-end investment company shares, and regarding prospectus disclosure of sales loads and revenue sharing arrangements, as if those requirements applied to each Fund. In addition, each Fund will contractually require that any distributor of the Fund's Shares comply with such requirements in connection with the distribution of such Fund's Shares.

12. Applicants state that each Fund may impose an EWC on Shares submitted for repurchase that have been held less than a specified period and may grant waivers of the EWCs on repurchases in connection with certain categories of shareholders or transactions established from time to time. Applicants state that each Fund will apply the EWC (and any waivers, scheduled variations or eliminations of the EWC) uniformly to all shareholders in a given class and consistently with the requirements of rule 22d–1 under the Act as if the Funds were open-end investment companies.

13. Each Fund operating as an interval fund pursuant to rule 23c–3 under the Act may offer its shareholders an exchange feature under which the shareholders of the Fund may, in connection with such Fund's periodic repurchase offers, exchange their Shares of the Fund for shares of the same class of (i) registered open-end investment companies, or (ii) other registered closed-end investment companies that comply with rule 23c–3 under the Act and continuously offer their shares at net asset value, that are in the Fund's group of investment companies (collectively, the ''Other Funds''). Shares of a Fund operating pursuant to rule 23c–3 that are exchanged for shares of Other Funds will be included as part of the amount of the repurchase offer amount for such Fund as specified in rule 23c–3 under the Act. Any exchange option will comply with rule 11a–3 under the Act, as if the Fund were an open-end investment company subject to rule 11a–3. In complying with rule 11a–3, each Fund will treat an EWC as if it were a contingent deferred sales load (''CDSL'').

Applicants' Legal Analysis

Multiple Classes of Shares

1. Section 18(a)(2) of the Act provides that a closed-end investment company may not issue or sell a senior security that is a stock unless certain requirements are met. Applicants state that the creation of multiple classes of Shares of the Funds may violate section 18(a)(2) because the Funds may not meet such requirements with respect to a class of Shares that may be a senior security.

2. Section 18(c) of the Act provides, in relevant part, that a registered closed-end investment company may not issue or sell any senior security if, immediately thereafter, the company has outstanding more than one class of senior security. Applicants state that the multi-class system proposed in the Application may result in Shares of a class having ''priority over another class as to payment of dividends,'' and being deemed a ''senior security,'' because shareholders of different classes would pay different distribution and/or service fees, different administrative fees and any other incremental expenses that should be properly allocated to a particular class. Accordingly, applicants state that the creation of multiple classes of Shares of a Fund with different fees and expenses may be prohibited by section 18(c).

3. Section 18(i) of the Act provides, in relevant part, that each share of stock issued by a registered management investment company will be a voting stock and have equal voting rights with every other outstanding voting stock. Applicants state that multiple classes of Shares of the Funds may violate section 18(i) of the Act because each class would be entitled to exclusive voting rights with respect to matters solely related to that class.

4. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction or any class or classes of persons, securities or transactions from any provision of the Act, or from any rule or regulation under the Act, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request an exemption under section 6(c) from sections 18(a)(2), 18(c) and 18(i) to permit the Funds to issue multiple classes of Shares.

5. Applicants submit that the proposed allocation of expenses relating to distribution and/or service arrangements and voting rights among multiple classes is equitable and will not discriminate against any group or class of shareholders. Applicants submit that the proposed arrangements would permit a Fund to facilitate the distribution of its securities and provide investors with a broader choice of shareholder services. Applicants assert that the proposed closed-end

[4] Applicants submit that rule 23c–3 and Regulation M under the Exchange Act permit an interval fund to make repurchase offers to repurchase its shares while engaging in a continuous offering of its shares pursuant to Rule 415 under the Securities Act of 1933, as amended.

[5] All references in the application to the FINRA Sales Charge Rule includes any successor or replacement to the FINRA Sales Charge Rule.

[6] In all respects other than class-by-class disclosure, each Fund will comply with the requirements of Form N–2.

[7] *See* Shareholder Reports and Quarterly Portfolio Disclosure of Registered Management Investment Companies, Investment Company Act Release No. 26372 (Feb. 27, 2004) (adopting release) (requiring open-end investment companies to disclose fund expenses in shareholder reports); and Disclosure of Breakpoint Discounts by Mutual Funds, Investment Company Act Release No. 26464 (June 7, 2004) (adopting release) (requiring open-end investment companies to provide prospectus disclosure of certain sales load information).

[8] Fund of Funds Investments, Investment Company Act Rel. Nos. 26198 (Oct. 1, 2003) (proposing release) and 27399 (Jun. 20, 2006) (adopting release). *See also* Rules 12d1–1, *et seq.* of the Act.

investment company multiple class structure does not raise the concerns underlying section 18 of the Act to any greater degree than open-end investment companies' multiple class structures that are permitted by rule 18f–3 under the Act. Applicants state that each Fund will comply with the provisions of rule 18f–3 as if it were an open-end investment company.

Early Withdrawal Charges

1. Section 23(c) of the Act provides, in relevant part, that no registered closed-end investment company shall purchase securities of which it is the issuer, except: (a) On a securities exchange or other open market; (b) pursuant to tenders, after reasonable opportunity to submit tenders given to all holders of securities of the class to be purchased; or (c) under other circumstances as the Commission may permit by rules and regulations or orders for the protection of investors.

2. Rule 23c–3 under the Act permits a registered closed-end investment company (an ''interval fund'') to make repurchase offers of between five and twenty-five percent of its outstanding shares at net asset value at periodic intervals pursuant to a fundamental policy of the interval fund. Rule 23c–3(b)(1) under the Act permits an interval fund to deduct from repurchase proceeds only a repurchase fee, not to exceed two percent of the proceeds, that is paid to the interval fund and is reasonably intended to compensate the fund for expenses directly related to the repurchase.

3. Section 23(c)(3) provides that the Commission may issue an order that would permit a closed-end investment company to repurchase its shares in circumstances in which the repurchase is made in a manner or on a basis that does not unfairly discriminate against any holders of the class or classes of securities to be purchased.

4. Applicants request relief under section 6(c), discussed above, and section 23(c)(3) from rule 23c–3 to the extent necessary for the Funds to impose EWCs on Shares of the Funds submitted for repurchase that have been held for less than a specified period.

5. Applicants state that the EWCs they intend to impose are functionally similar to CDSLs imposed by open-end investment companies under rule 6c–10 under the Act. Rule 6c–10 permits open-end investment companies to impose CDSLs, subject to certain conditions. Applicants note that rule 6c–10 is grounded in policy considerations supporting the employment of CDSLs where there are adequate safeguards for the investor, and state that the same policy considerations support imposition of EWCs in the interval fund context. In addition, applicants state that EWCs may be necessary for the distributor to recover distribution costs. Applicants represent that any EWC imposed by the Funds will comply with rule 6c–10 under the Act as if the rule were applicable to closed-end funds. Applicants further represent that each Fund will disclose EWCs in accordance with the requirements of Form N–1A concerning CDSLs as if the Fund were an open-end investment company.

Asset-Based Distribution and/or Service Fees

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit an affiliated person of a registered investment company, or an affiliated person of such person, acting as principal, from participating in or effecting any transaction in connection with any joint enterprise or joint arrangement in which the investment company participates unless the Commission issues an order permitting the transaction. In reviewing applications submitted under section 17(d) and rule 17d–1, the Commission considers whether the participation of the investment company in a joint enterprise or joint arrangement is consistent with the provisions, policies and purposes of the Act, and the extent to which the participation is on a basis different from or less advantageous than that of other participants.

2. Rule 17d–3 under the Act provides an exemption from section 17(d) and rule 17d–1 to permit open-end investment companies to enter into distribution arrangements pursuant to rule 12b–1 under the Act. Applicants request an order under section 17(d) and rule 17d–1 under the Act to the extent necessary to permit the Funds to impose asset-based distribution and/or service fees. Applicants represent that the Funds will comply with rules 12b–1 and 17d–3 as if those rules applied to closed-end investment companies, which they believe will resolve any concerns that might arise in connection with a Fund financing the distribution of its Shares through asset-based distribution and/or service fees.

3. For the reasons stated above, Applicants submit that the exemptions requested under section 6(c) of the Act are necessary and appropriate in the public interest and are consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants further submit that the relief requested pursuant to section 23(c)(3) of the Act will be consistent with the protection of investors and will insure that Applicants do not unfairly discriminate against any holders of the class of securities to be purchased. Finally, Applicants state that the Funds' imposition of asset-based distribution and/or service fees is consistent with the provisions, policies and purposes of the Act and does not involve participation on a basis different from or less advantageous than that of other participants.

Applicants' Condition

Applicants agree that any order granting the requested relief will be subject to the following condition:

Each Fund relying on the order will comply with the provisions of rules 6c–10, 12b–1, 17d–3, 18f–3, 22d–1, and, where applicable, 11a–3 under the Act, as amended from time to time, as if those rules applied to closed-end management investment companies, and will comply with the FINRA Sales Charge Rule, as amended from time to time, as if that rule applied to all closed-end management investment companies.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24295 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–101, OMB Control No. 3235–0082]

Proposed Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Form 11–K

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form 11–K (17 CFR 249.311) is the annual report designed for use by employee stock purchase, savings and similar plans to comply with the

reporting requirements under Section 15(d) of the Securities and Exchange Act of 1934 (the ''Exchange Act'') (15 U.S.C. 78o(d)). Section 15(d) establishes a periodic reporting obligation for every issuer of a class of securities registered under the Securities Act of 1933 (the ''Securities Act'') (15 U.S.C. 77a *et seq.*). Form 11–K provides employees of an issuer with financial information so that they can assess the performance of the investment vehicle or stock plan. Form 11–K takes approximately 30 burden hours per response and is filed by 1,302 respondents for total of 39,060 burden hours (30 hours per response × 1,302 responses).

Written comments are invited on: (a) Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

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 control number.

Please direct your written comment to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24133 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93500; File No. SR–CBOE–2021–064]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Extend the Operation of Its Flexible Exchange Options (''FLEX Options'') Pilot Program Regarding Permissible Exercise Settlement Values for FLEX Index Options

November 1, 2021.

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 October 29, 2021, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I 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 extend the operation of its Flexible Exchange Options (''FLEX Options'') pilot program regarding permissible exercise settlement values for FLEX Index Options. The text of the proposed rule change is provided below.

(additions are *italicized;* deletions are [bracketed])

* * * * *

Rules of Cboe Exchange, Inc.

* * * * *

Rule 4.21. Series of FLEX Options

(a) No change.

(b) *Terms.* When submitting a FLEX Order for a FLEX Option series to the System, the submitting FLEX Trader must include one of each of the following terms in the FLEX Order (all other terms of a FLEX Option series are the same as those that apply to non-FLEX Options), provided that a FLEX Index Option with an index multiplier of one may not be the same type (put or call) and may not have the same exercise style, expiration date, settlement type, and exercise price as a non-FLEX Index Option overlying the same index listed for trading (regardless of the index multiplier of the non-FLEX Index Option), which terms constitute the FLEX Option series:

(1)–(4) No change.

(5) settlement type:

(A) No change.

(B) *FLEX Index Options.* FLEX Index Options are settled in U.S. dollars, and may be:

(i) No change.

(ii) p.m.-settled (with exercise settlement value determined by reference to the reported level of the index derived from the reported closing prices of the component securities), except for a FLEX Index Option that expires on any business day that falls on or within two business days of a third Friday-of-the-month expiration day for a non-FLEX Option (other than a QIX option) may only be a.m.-settled; however, for a pilot period ending the earlier of [November 1, 2021]*May 2, 2022* or the date on which the pilot program is approved on a permanent basis, a FLEX Index Option with an expiration date on the third-Friday of the month may be p.m.-settled;

(iii)–(iv) No change.

* * * * *

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.

[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).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On January 28, 2010, the Securities and Exchange Commission (the ''Commission'') approved a Cboe Options rule change that, among other things, established a pilot program regarding permissible exercise settlement values for FLEX Index Options.[5] The Exchange has extended the pilot period numerous times, which is currently set to expire on the earlier of November 1, 2021 or the date on which the pilot program is approved on a permanent basis.[6] The purpose of this rule change filing is to extend the pilot program through the earlier of May 2, 2022 or the date on which the pilot program is approved on a permanent basis. This filing simply seeks to extend the operation of the pilot program and does not propose any substantive changes to the pilot program.

Under Rule 4.21(b), *Series of FLEX Options* (regarding terms of a FLEX Option),[7] a FLEX Option may expire on any business day (specified to day, month and year) no more than 15 years from the date on which a FLEX Trader submits a FLEX Order to the System.[8] FLEX Index Options are settled in U.S. dollars, and may be a.m.-settled (with exercise settlement value determined by reference to the reported level of the index derived from the reported opening prices of the component securities) or p.m.-settled (with exercise settlement value determined by reference to the reported level of the index derived from the reported closing prices of the component securities).[9] Specifically, a FLEX Index Option that expires on, or within two business days of, a third Friday-of-the-month expiration day for a non-FLEX Option (other than a QIX option), may only be a.m. settled.[10] However, under the exercise settlement values pilot, this restriction on p.m.-settled FLEX Index Options was eliminated.[11] As stated, the exercise settlement values pilot is currently set to expire on the earlier of November 1, 2021 or the date on which the pilot program is approved on a permanent basis.

Cboe Options is proposing to extend the pilot program through the earlier of May 2, 2022 or the date on which the pilot program is approved on a permanent basis. Cboe Options believes the pilot program has been successful and well received by its Trading Permit Holders and the investing public for the period that it has been in operation as a pilot. In support of the proposed extension of the pilot program, and as required by the pilot program's Approval Order, the Exchange has submitted to the Commission pilot program reports regarding the pilot, which detail the Exchange's experience with the program. Specifically, the Exchange provided the Commission with annual reports analyzing volume and open interest for each broad-based FLEX Index Options class overlying a third Friday-of-the-month expiration day, p.m.-settled FLEX Index Options series.[12] The annual reports also contained information and analysis of FLEX Index Options trading patterns. The Exchange also provided the Commission, on a periodic basis, interim reports of volume and open interest.

The Exchange believes there is sufficient investor interest and demand in the pilot program to warrant its extension. The Exchange believes that, for the period that the pilot has been in operation, the program has provided investors with additional means of managing their risk exposures and carrying out their investment objectives. Furthermore, the Exchange believes that it has not experienced any adverse market effects with respect to the pilot program, including any adverse market volatility effects that might occur as a result of large FLEX exercises in FLEX Option series that expire near Non-FLEX expirations and use a p.m. settlement (as discussed below).

In that regard, based on the Exchange's experience in trading FLEX Options to date and over the pilot period, Cboe Options continues to believe that the restrictions on exercise settlement values are no longer necessary to insulate Non-FLEX expirations from the potential adverse market impacts of FLEX expirations.[13]

[5] Securities Exchange Act Release No. 61439 (January 28, 2010), 75 FR 5831 (February 4, 2010) (SR–CBOE–2009–087) (''Approval Order''). The initial pilot period was set to expire on March 28, 2011, which date was added to the rules in 2010. *See* Securities Exchange Act Release No. 61676 (March 9, 2010), 75 FR 13191 (March 18, 2010) (SR–CBOE–2010–026).

[6] *See* Securities Exchange Act Release Nos. 64110 (March 23, 2011), 76 FR 17463 (March 29, 2011) (SR–CBOE–2011–024); 66701 (March 30, 2012), 77 FR 20673 (April 5, 2012) (SR–CBOE–2012–027); 68145 (November 2, 2012), 77 FR 67044 (November 8, 2012) (SR–CBOE–2012–102); 70752 (October 24, 2013), 78 FR 65023 (October 30, 2013) (SR–CBOE–2013–099); 73460 (October 29, 2014), 79 FR 65464 (November 4, 2014) (SR–CBOE–2014–080); 77742 (April 29, 2016), 81 FR 26857 (May 4, 2016) (SR–CBOE–2016–032); 80443 (April 12, 2017), 82 FR 18331 (April 18, 2017) (SR–CBOE–2017–032); 83175 (May 4, 2018), 83 FR 21808 (May 10, 2018) (SR–CBOE–2018–037); 84537 (November 5, 2018), 83 FR 56113 (November 9, 2018) (SR–CBOE–2018–071); 85707 (April 23, 2019), 84 FR 18100 (April 29, 2019) (SR–CBOE–2019–021); 87515 (November 13, 2020), 84 FR 63945 (November 19, 2019) (SR–CBOE–2019–108); 88782 (April 30, 2020), 85 FR 27004 (May 6, 2020) (SR–CBOE–2020–039); 90279 (October 28, 2020), 85 FR 69667 (November 3, 2020) (SR–CBOE–2020–103); *and* 91782 (May 5, 2021), 86 FR 25915 (May 11, 2021) (SR–CBOE–2021–031) (extending the pilot program through the earlier of November 1, 2021 or the date on which the pilot program is approved on a permanent basis). At the same time the permissible exercise settlement values pilot was established for FLEX Index Options, the Exchange also established a pilot program eliminating the minimum value size requirements for all FLEX Options. *See* Approval Order, *supra* note 5. The pilot program eliminating the minimum value size requirements was extended twice pursuant to the same rule filings that extended the permissible exercise settlement values (for the same extended periods) and was approved on a permanent basis in a separate rule change filing. *See id; and* Securities Exchange Act Release No. 67624 (August 8, 2012), 77 FR 48580 (August 14, 2012) (SR–CBOE–2012–040) (Order Granting Approval of Proposed Rule Change Related to Permanent Approval of Its Pilot on FLEX Minimum Value Sizes).

[7] In 2019, prior Rule 24A.4.01, covering the pilot program, was relocated to current Rule 4.21(b)(5). *See* Securities Exchange Act Release No. 87235 (October 4, 2019), 84 FR 54671 (October 10, 2019) (SR–CBOE–2019–084).

[8] Except an Asian-settled or Cliquet-settled FLEX Option series, which must have an expiration date that is a business day but may only expire 350 to 371 days (which is approximately 50 to 53 calendar weeks) from the date on which a FLEX Trader submits a FLEX Order to the System.

[9] *See* Rule 4.21(b)(5)(B); *see also* Securities Exchange Act Release No. 87235 (October 4, 2019), 84 FR 54671 (October 10, 2019) (SR–CBOE–2019–084). The rule change removed the provision regarding the exercise settlement value of FLEX Index Options on the NYSE Composite Index, as the Exchange no longer lists options on that index for trading, and included the provisions regarding how the exercise settlement value is determined for each settlement type, as how the exercise settlement value is determined is dependent on the settlement type.

[10] For example, notwithstanding the pilot, the exercise settlement value of a FLEX Index Option that expires on the Tuesday before the third Friday-of-the-month could be a.m. or p.m. settled. However, the exercise settlement value of a FLEX Index Option that expires on the Wednesday before the third Friday-of-the-month could only be a.m. settled.

[11] No change was necessary or requested with respect to FLEX Equity Options. Regardless of the expiration date, FLEX Equity Options are settled by physical delivery of the underlying.

[12] The annual reports also contained certain pilot period and pre-pilot period analyses of volume and open interest for third Friday-of-the-month expiration days, a.m.-settled FLEX Index series and third Friday-of-the-month expiration day Non-FLEX Index series overlying the same index as a third Friday-of-the-month expiration day, p.m.-settled FLEX Index option.

[13] In further support, the Exchange also notes that the p.m. settlements are already permitted for FLEX Index Options on any other business day except on, or within two business days of, the third Friday-of-the-month. The Exchange is not aware of any market disruptions or problems caused by the use of these settlement methodologies on these expiration dates (or on the expiration dates addressed under the pilot program). The Exchange is also not aware of any market disruptions or

Continued

To the contrary, Cboe Options believes that the restriction actually places the Exchange at a competitive disadvantage to its OTC counterparts in the market for customized options, and unnecessarily limits market participants' ability to trade in an exchange environment that offers the added benefits of transparency, price discovery, liquidity, and financial stability.

The Exchange also notes that certain position limit, aggregation and exercise limit requirements continue to apply to FLEX Index Options in accordance with Rules 8.35, *Position Limits for FLEX Options,* 8.42(g) *Exercise Limits* (in connection with FLEX Options) and 8.43(j), *Reports Related to Position Limits* (in connection with FLEX Options). Additionally, all FLEX Options remain subject to the general position reporting requirements in Rule 8.43(a).[14] Moreover, the Exchange and its Trading Permit Holder organizations each have the authority, pursuant to Rule 10.9, *Margin Required is Minimum,* to impose additional margin as deemed advisable. Cboe Options continues to believe these existing safeguards serve sufficiently to help monitor open interest in FLEX Option series and significantly reduce any risk of adverse market effects that might occur as a result of large FLEX exercises in FLEX Option series that expire near Non-FLEX expirations and use a p.m. settlement.

Cboe Options is also cognizant of the OTC market, in which similar restrictions on exercise settlement values do not apply. Cboe Options continues to believe that the pilot program is appropriate and reasonable and provides market participants with additional flexibility in determining whether to execute their customized options in an exchange environment or in the OTC market. Cboe Options continues to believe that market participants benefit from being able to trade these customized options in an exchange environment in several ways, including, but not limited to, enhanced efficiency in initiating and closing out positions, increased market transparency, and heightened contra-party creditworthiness due to the role of the Options Clearing Corporation as issuer and guarantor of FLEX Options.

If, in the future, the Exchange proposes an additional extension of the pilot program, or should the Exchange propose to make the pilot program permanent, the Exchange will submit, along with any filing proposing such amendments to the pilot program, an annual report (addressing the same areas referenced above and consistent with the pilot program's Approval Order) to the Commission at least two months prior to the expiration date of the program. The Exchange is required to submit an annual report at least yearly. Currently, the Exchange provides annual reports that cover the period from August 1st to July 31st of the applicable year. The Exchange will continue to provide reports covering this period annually and any additional report at least two months prior to the expiration date of the program covering the full prior year in the case that the Exchange is requesting permanent approval of the program.[15] The Exchange will also continue, on a periodic basis, to submit interim reports of volume and open interest consistent with the terms of the exercise settlement values pilot program as described in the pilot program's Approval Order.[16] Additionally, the Exchange will provide the Commission with any additional data or analyses the Commission requests because it deems such data or analyses necessary to determine whether the pilot program is consistent with the Exchange Act. The Exchange is in the process of making public on its website all data and analyses previously submitted to the Commission under the pilot program, and will make public any data and analyses it submits to the Commission under the pilot program in the future.[17]

As noted in the pilot program's Approval Order, any positions established under the pilot program would not be impacted by the expiration of the pilot program.[18]

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.[19] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[20] 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

problems caused by the use of customized options in the over-the-counter (''OTC'') markets that expire on or near the third Friday-of-the-month and are p.m. settled. In addition, the Exchange believes the reasons for limiting expirations to a.m. settlement, which is something the SEC has imposed since the early 1990s for Non-FLEX Options, revolved around a concern about expiration pressure on the New York Stock Exchange (''NYSE'') at the close that are no longer relevant in today's market. Today, the Exchange believes stock exchanges are able to better handle volume. There are multiple primary listing and unlisted trading privilege (''UTP'') markets, and trading is dispersed among several exchanges and alternative trading systems. In addition, the Exchange believes that surveillance techniques are much more robust and automated. In the early 1990s, it was also thought by some that opening procedures allow more time to attract contra-side interest to reduce imbalances. The Exchange believes, however, that today, order flow is predominantly electronic and the ability to smooth out openings and closes is greatly reduced (*e.g.,* market-on-close procedures work just as well as openings). Also, other markets, such as the NASDAQ Stock Exchange, do not have the same type of pre-opening imbalance disseminations as NYSE, so many stocks are not subject to the same procedures on the third Friday-of-the-month. In addition, the Exchange believes that NYSE has reduced the required time a specialist has to wait after disseminating a pre-opening indication. So, in this respect, the Exchange believes there is less time to react in the opening than in the close. Moreover, to the extent there may be a risk of adverse market effects attributable to p.m. settled options that would otherwise be traded in a non-transparent fashion in the OTC market, the Exchange continues to believe that such risk would be lessened by making these customized options eligible for trading in an exchange environment because of the added transparency, price discovery, liquidity, and financial stability available.

[14] Rule 8.43(a) provides that ''[i]n a manner and form prescribed by the Exchange, each Trading Permit Holder shall report to the Exchange, the name, address, and social security or tax identification number of any customer who, acting alone, or in concert with others, on the previous business day maintained aggregate long or short positions on the same side of the market of 200 or more contracts of any single class of option contracts dealt in on the Exchange. The report shall indicate for each such class of options, the number of option contracts comprising each such position and, in the case of short positions, whether covered or uncovered.'' For purposes of Rule 8.43, the term ''customer'' in respect of any Trading Permit Holder includes ''the Trading Permit Holder, any general or special partner of the Trading Permit Holder, any officer or director of the Trading Permit Holder, or any participant, as such, in any joint, group or syndicate account with the Trading Permit Holder or with any partner, officer or director thereof.'' Rule 8.43(d).

[15] For example, if the Exchange plans on submitting a proposal in April 2022 requesting permanent approval of the pilot program expiring May 2, 2022, the Exchange would have to submit an annual report no later than March 2, 2022 covering the full prior year.

[16] The Exchange is required to submit the interim reports on a quarterly basis within 15 days of the end of each calendar quarter that the pilot is in effect.

[17] Available at *https://www.cboe.com/aboutcboe/legal-regulatory/national-market-system-plans/pm-settlement-flex-pm-data.*

[18] For example, a position in a p.m.-settled FLEX Index Option series that expires on the third Friday-of-the-month in January 2020 could be established during the exercise settlement values pilot. If the pilot program were not extended (or made permanent), then the position could continue to exist. However, the Exchange notes that any further trading in the series would be restricted to transactions where at least one side of the trade is a closing transaction. *See* Approval Order at footnote 3, *supra* note 5.

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(5).

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)[21] 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 that the proposed extension of the pilot program, which permits an additional exercise settlement value, would provide greater opportunities for investors to manage risk through the use of FLEX Options. Further, the Exchange believes that it has not experienced any adverse effects from the operation of the pilot program, including any adverse market volatility effects that might occur as a result of large FLEX exercises in FLEX Option series that expire near Non-FLEX expirations and are p.m.-settled. The Exchange also believes that the extension of the exercise settlement values pilot does not raise any unique regulatory concerns. In particular, although p.m. settlements may raise questions with the Commission, the Exchange believes that, based on the Exchange's experience in trading FLEX Options to date and over the pilot period, market impact and investor protection concerns will not be raised by this rule change. The Exchange also believes that the proposed rule change would continue to provide Trading Permit Holders and investors with additional opportunities to trade customized options in an exchange environment (which offers the added benefits of transparency, price discovery, liquidity, and financial stability as compared to the over-the-counter market) and subject to exchange-based rules, and investors would benefit as a result.

B. Self-Regulatory Organization's Statement on Burden on Competition

Cboe Options does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes there is sufficient investor interest and demand in the pilot program to warrant its extension. The Exchange believes that, for the period that the pilot has been in operation, the program has provided investors with additional means of managing their risk exposures and carrying out their investment objectives. Furthermore, the Exchange believes that it has not experienced any adverse market effects with respect to the pilot program, including any adverse market volatility effects that might occur as a result of large FLEX exercises in FLEX Option series that expire near Non-Flex expirations and use a p.m. settlement. Cboe Options believes that the restriction actually places the Exchange at a competitive disadvantage to its OTC counterparts in the market for customized options, and unnecessarily limits market participants' ability to trade in an exchange environment that offers the added benefits of transparency, price discovery, liquidity, and financial stability. Therefore, the Exchange does not believe that the proposed rule change will impose any burden on competition.

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

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[22] and Rule 19b–4(f)(6) thereunder.[23]

A proposed rule change filed under Rule 19b–4(f)(6)[24] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii),[25] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that such waiver will allow the Exchange to extend the pilot program and maintain the status quo, thereby reducing market disruption.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the pilot program to continue uninterrupted, thereby avoiding investor confusion that could result from a temporary interruption in the pilot program. For this reason, the Commission designates the proposed rule change to be operative upon filing.[26]

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–CBOE–2021–064 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2021–064. 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

[21] *Id.*

[22] 15 U.S.C. 78s(b)(3)(A).

[23] 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 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. The Exchange has satisfied this requirement.

[24] 17 CFR 240.19b–4(f)(6).

[25] 17 CFR 240.19b–4(f)(6)(iii).

[26] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–CBOE–2021–064, and should be submitted on or before November 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24169 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–638, OMB Control No. 3235–0687]

Submission Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 239

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Rule 239 (17 CFR 230.239) provides exemptions under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*), the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) and the Trust Indenture Act of 1939 (U.S.C. 77aaa *et seq.*) for security-based swaps issued by certain clearing agencies satisfying certain conditions. The purpose of the information required by Rule 239 is to make certain information about security-based swaps that may be cleared by the registered or the exempt clearing agencies available to eligible contract participants and other market participants. We estimate that each registered or exempt clearing agency issuing security-based swaps in its function as a central counterparty will spend approximately 2 hours each time it provides or update the information in its agreements relating to security-based swaps or on its website. We estimate that each registered or exempt clearing agency will provide or update the information approximately 20 times per year. In addition, we estimate that 75% of the 2 hours per response (1.5 hours) is prepared internally by the clearing agency for a total annual reporting burden of 180 hours (1.5 hours per response × 20 times × 6 respondents).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24145 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93489; File No. SR–NYSEArca–2021–31]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the Valkyrie Bitcoin Fund Under NYSE Arca Rule 8.201–E

November 1, 2021.

On April 23, 2021, NYSE Arca, Inc. (''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the Valkyrie Bitcoin Fund under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares). The proposed rule change was published for comment in the **Federal Register** on May 12, 2021.[3]

On June 22, 2021, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On August 9, 2021, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act[6] to determine whether to approve or disapprove the proposed rule change.[7]

Section 19(b)(2) of the Act[8] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for comment in

[27] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 91771 (May 6, 2021), 86 FR 26073 (May 12, 2021). Comments on the proposed rule change can be found at: *https://www.sec.gov/comments/sr-nysearca-2021-31/srnysearca202131.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 92233 (June 22, 2021), 86 FR 34107 (June 28, 2021).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 92610 (Aug. 9, 2021), 86 FR 44763 (Aug. 13, 2021).

[8] 15 U.S.C. 78s(b)(2).

the **Federal Register** on May 12, 2021.[9] The 180th day after publication of the proposed rule change is November 8, 2021. The Commission is extending the time period for approving or disapproving the proposed rule change for an additional 60 days.

The Commission finds that it is appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised in the comment letters that have been submitted in connection therewith. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[10] designates January 7, 2022, as the date by which the Commission shall either approve or disapprove the proposed rule change (File Number SR–NYSEArca–2021–31).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24167 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–71; OMB Control No. 3235–0058]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549

Extension:
Form 12b–25

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

The purpose of Form 12b–25 is to provide notice to the Commission and the marketplace that a public company will be unable to timely file a required periodic report. If all filing conditions are met, the company is granted an automatic filing extension. Form 12b–25 is filed by publicly held companies. Approximately 7,799 issuers file Form 12b–25 and it takes approximately 2.5 hours per response for a total of 19,498 burden hours.

Written comments are invited on: (a) Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, C/O John R. Pezzullo, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24147 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–216, OMB Control No. 3235–0243]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 206(3)–2

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 206(3)–2, (17 CFR 275.206(3)–2) which is entitled ''Agency Cross Transactions for Advisory Clients,'' permits investment advisers to comply with section 206(3) of the Investment Advisers Act of 1940 (the ''Act'') (15 U.S.C. 80b–6(3)) by obtaining a client's blanket consent to enter into agency cross transactions (*i.e.,* a transaction in which an adviser acts as a broker to both the advisory client and the opposite party to the transaction). Rule 206(3)–2 applies to all registered investment advisers. In relying on the rule, investment advisers must provide certain disclosures to their clients. Advisory clients can use the disclosures to monitor agency cross transactions that affect their advisory account. The Commission also uses the information required by Rule 206(3)-2 in connection with its investment adviser inspection program to ensure that advisers are in compliance with the rule. Without the information collected under the rule, advisory clients would not have information necessary for monitoring their adviser's handling of their accounts and the Commission would be less efficient and effective in its inspection program.

The information requirements of the rule consist of the following: (1) Prior to obtaining the client's consent, appropriate disclosure must be made to the client as to the practice of, and the conflicts of interest involved in, agency cross transactions; (2) at or before the completion of any such transaction, the client must be furnished with a written confirmation containing specified information and offering to furnish upon request certain additional information; and (3) at least annually, the client must be furnished with a written statement or summary as to the total number of transactions during the period covered by the consent and the total amount of commissions received by the adviser or its affiliated broker-dealer attributable to such transactions.

The Commission estimates that approximately 378 respondents use the rule annually, necessitating about 50 responses per respondent each year, for a total of 18,900 responses. Each response requires an estimated 0.5 hours, for a total of 9,450 hours. The estimated average burden hours are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or representative survey or study of the cost of Commission rules and forms.

This collection of information is found at (17 CFR 275.206(3)–2) and is necessary in order for the investment adviser to obtain the benefits of Rule 206(3)–2. The collection of information requirements under the rule is mandatory. Information subject to the disclosure requirements of Rule 206(3)–2 does not require submission to the Commission; and, accordingly, the disclosure pursuant to the rule is not kept confidential.

[9] *See supra* note 3.

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(57).

Commission-registered investment advisers are required to maintain and preserve certain information required under Rule 206(3)–2 for five (5) years. The long-term retention of these records is necessary for the Commission's inspection program to ascertain compliance with the Advisers Act.

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 control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) >*www.reginfo.gov/public/do/PRAMain*< and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24131 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–360, OMB Control No. 3235–0409]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rules 17Ad–15

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 17Ad–15 (17 CFR 240.17Ad–15) (''Rule 17Ad–15'') under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act'').

Rule 17Ad–15 requires every registered transfer agent to establish written standards for the acceptance of guarantees of securities transfers from eligible guarantor institutions. Every registered transfer agent is also required to establish procedures, including written guidelines where appropriate, to ensure that the transfer agent uses those standards to determine whether to accept or reject guarantees from eligible guarantor institutions. In implementing these requirements, the Commission's purpose is to ensure that registered transfer agents treat eligible guarantor institutions equitably.

Additionally, Rule 17Ad–15 requires every registered transfer agent to make and maintain records in the event the transfer agent determines to reject signature guarantees from eligible guarantor institutions. Registered transfer agents' records must include, following the date of rejection, a record of the rejected transfer, along with the reason for rejection, the identification of the guarantor, and an indication whether the guarantor failed to meet the transfer agent's guarantee standards.

Rule 17Ad–15 requires registered transfer agents to maintain these records for a period of three years. The Commission designed these mandatory recordkeeping requirements to assist the Commission and other regulatory agencies with monitoring registered transfer agents and ensuring compliance with the rule. This rule does not involve the collection of confidential information.

The Commission estimates that approximately 366 registered transfer agents will spend a total of approximately 14,640 hours per year complying with recordkeeping requirements of Rules 17Ad–15 (40 hours per year per registered transfer agent).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to

(i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24129 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93486; File No. SR–Phlx–2021–67]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Equity 4, Rule 3301B

November 1, 2021.

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 October 25, 2021, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''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 Equity 4, Rule 3301B, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Presently, the Exchange is making functional enhancements and improvements to specific Order Types [3] and Order Attributes [4] that are currently only available via the RASH Order entry protocol.[5] Specifically, the Exchange will be upgrading the logic and implementation of these Order Types and Order Attributes so that the features are more streamlined across the Exchange Systems and order entry protocols, and will enable the Exchange to process these Orders more quickly and efficiently. Additionally, this System upgrade will pave the way for the Exchange to enhance the OUCH Order entry protocol [6] so that Participants may enter such Order Types and Order Attributes via OUCH, in addition to the RASH Order entry protocols.[7] The Exchange plans to implement its enhancement of the OUCH protocol sequentially, by Order Type and Order Attribute.[8]

To support and prepare for these upgrades and enhancements, the Exchange recently submitted three rule filings to the Commission that amended its rules pertaining to, among other things, Market Maker Peg Orders, Orders with Reserve Size, and Orders with Pegging and Trade Now Attributes.[9] The Exchange now proposes to further amend its Rules governing the Discretion Order Attribute, at Rule 3301B(g), so that it aligns with how the System, once upgraded, will handle these Orders with Discretion going forward.

As set forth in Rule 3301B(g), Discretion is an Order Attribute under which an Order has a non-displayed discretionary price range within which the entering Participant is willing to trade. Presently, the Rule provides that the System will process Discretionary Orders, upon entry, by generating a Non-Displayed Order with a Time-in-Force of Immediate-or-Cancel (a ''Discretionary IOC'') that will attempt to access liquidity available within the discretionary price range. The System will not permit the Discretionary IOC to execute, however, if the price of the execution would trade through a Protected Quotation. If more than one Order with Discretion satisfies conditions that would cause the generation of a Discretionary IOC simultaneously, the order in which such Discretionary IOCs will be presented for execution is random, based on the respective processing time for each such Order. Whenever a Discretionary IOC is generated, the underlying Order with Discretion will be withheld or removed from the Exchange's Book and will then be routed and/or placed on the Exchange's Book if the Discretionary IOC does not exhaust the full size of the underlying Order with Discretion, with its price determined by the underlying Order Type and Order Attributes selected by the Participant. In addition to prescribing a procedure for handling Discretionary Orders generally, the existing Rule also describes special procedures for handling Discretionary Orders with various types of Routing Attributes and with pegged discretionary price ranges.

The Exchange proposes to amend the process by which it processes Discretionary Orders in several respects.[10] First, the Exchange proposes to clarify existing text which states that ''[a] Participant may also specify a limit price beyond which the discretionary price range does not extend.'' The Exchange intended for this clause to address the specific scenario where a Participant enters a Discretionary Order with a Discretionary Pegging Attribute, but the existing text is not explicit in this regard and thus is amenable to confusion. The Exchange proposes to restate this provision as follows to make its intention explicit: ''[a] Participant may also specify a limit on the discretionary price range of an Order that is entered with a Discretionary Pegging Attribute,'' and then further clarify the outcome of setting such a limit by stating ''beyond which the discretionary pegged price may not extend.'' [11] The Exchange notes that it uses the word ''may'' in this provision rather than ''shall'' because for Discretionary Orders with Pegging Attributes, the Rules specify the discretionary range applicable to those Orders; setting a limit on how far that range is allowed to extend is optional.

As a further organizational matter, the Exchange proposes to consolidate the portion of the Rule that describes the general procedure for handling Discretionary Orders with the portion that described the process for handling Discretionary Orders without a Routing Attribute assigned to them. Because non-routed orders conform to the general procedure, it is redundant to restate the process.

Second, as to the substance of the general Discretionary Order handling procedures, the Exchange proposes the following changes. Rather than generate a Discretionary IOC immediately upon Order entry (regardless of available liquidity within the discretionary price range) and then post the unexecuted portion of the Discretionary Order on the Exchange's Book, the Exchange proposes instead to first, upon entry, execute the Discretionary Order against any previously posted Orders on the Exchange Book that are priced equal to

[3] An ''Order Type'' is a standardized set of instructions associated with an Order that define how it will behave with respect to pricing, execution, and/or posting to the Exchange Book when submitted to Exchange. *See* Equity 1, Section 1(b)(7) [sic].

[4] An ''Order Attribute'' is a further set of variable instructions that may be associated with an Order to further define how it will behave with respect to pricing, execution, and/or posting to the Exchange Book when submitted to Exchange. *See id.*

[5] The RASH (Routing and Special Handling) Order entry protocol is a proprietary protocol that allows member organizations to enter Orders, cancel existing Orders and receive executions. RASH allows participants to use advanced functionality, including discretion, random reserve, pegging and routing. See *http://nasdaqtrader.com/content/technicalsupport/specifications/TradingProducts/rash_sb.pdf.*

[6] The OUCH Order entry protocol is an Exchange proprietary protocol that allows subscribers to quickly enter orders into the System and receive executions. OUCH accepts limit Orders from member organizations, and if there are matching Orders, they will execute. Non-matching Orders are added to the Limit Order Book, a database of available limit Orders, where they are matched in price-time priority. OUCH only provides a method for member organizations to send Orders and receive status updates on those Orders. See *https://www.nasdaqtrader.com/Trader.aspx?id=OUCH.*

[7] The Exchange designed the OUCH protocol to enable member organizations to enter Orders quickly into the System. As such, the Exchange developed OUCH with simplicity in mind, and it therefore lacks more complex order handling capabilities. By contrast, the Exchange specifically designed RASH to support advanced functionality, including discretion, random reserve, pegging and routing. Once the System upgrades occur, then the Exchange intends to propose further changes to its Rules to permit participants to utilize OUCH, in addition to RASH, to enter order types that require advanced functionality.

[8] The Exchange notes that its sister exchange, the Nasdaq Stock Market, LLC, has filed an identical proposal, Securities Exchange Act Release No. 34–93245 (October 4, 2021), 86 FR 56302 (October 8, 2021) (SR–NASDAQ–2021–075); and Nasdaq BX, Inc. plans to do the same concurrent with this filing.

[9] *See* Securities Exchange Act Release No. 34–92377 (July 13, 2021), 86 FR 38147 (July 19, 2021) (SR–PHLX–2021–40); Securities Exchange Act Release No. 34–91263 (March 5, 2021), 86 FR 13950 (March 11, 2021) (SR–Phlx–2021–11); Securities Exchange Act Release No. 34–90558 (December 3, 2020), 85 FR 79231 (December 9, 2020) (SR–Phlx–2020–51).

[10] The Exchange proposes to replace certain existing references in the Rule from ''PSX'' to the ''Exchange'' or the ''System.'' This proposed change is non-substantive as these terms are synonymous.

[11] For example, a displayed Order to buy might have a limit price of $11.00 and a discretionary price range pegged to the Best Bid with a discretionary limit of $11.05. If the NBB is $11.02 at the time of entry, the order will be displayed at $11.00 with a discretionary price range up to $11.02. If the NBB later become $11.06, the Order will still be displayed at $11.00 and its discretionary price range will be capped at $11.05.

or better than the limit price of the Discretionary Order. If no such Order exists with which the Discretionary Order may fully execute upon entry, then the Exchange will post the Discretionary Order to the Exchange's Book in accordance with the parameters that apply to the underlying Order Type. In such case, the Exchange will generate a Discretionary IOC, with a price equal to the highest price for an Order to buy (lowest price for an Order to sell) within the discretionary price range and a size equal to the order available for execution, if and when the System determines that liquidity within the discretionary price range is available for execution. The Exchange will then execute the Discretionary IOC (provided that doing so would not trade-through a Protected Quotation). The Exchange proposes this change to increase the efficiency with which the Exchange processes Discretionary Orders. The Exchange intended for the existing process to enable Discretionary Orders to execute immediately within the discretionary price range upon entry, but in practice, the Exchange observes that they rarely do so. Attempts to locate available liquidity within the discretionary range immediately upon entry delay Discretionary Orders from entering the priority queue on the Exchange Book, resulting in an opportunity cost when no such liquidity is located. The proposed rule change will reorient the order handling process for Discretionary Orders so that it no longer sacrifices potential queue priority for attempts at possible immediate executions within the discretionary price range. Given that immediate executions of Discretionary Orders within the discretionary price range rarely occur, the Exchange does not believe that this change will have any material adverse impact on the performance of such Orders. Moreover, the Exchange will still allow for Discretionary Orders to attempt to execute against available liquidity immediately upon entry if contra-side liquidity, priced equal to or better than the limit price of the Discretionary Order, is resting on the Book at that time. And, if participants select a Time-in-Force of Immediate-or-Cancel for such Orders, then the orders will attempt to execute against available liquidity within the discretionary price range, which is unchanged from current functionality.

As noted above, whereas now, the Exchange generates a Discretionary IOC that is equal to the size of the Discretionary Order, and then posts shares to the Book that remain unexecuted after the Exchange executes the Discretionary IOC against available liquidity in the discretionary price range, the Exchange instead proposes to generate a Discretionary IOC that will be equal to the size of the available liquidity within the discretionary range, with any residual shares of the Discretionary Order remaining on the Book and retaining their existing priority. If the Discretionary IOC is not fully executed,[12] the posted portion of the Discretionary Order will be reentered on the Exchange Book as a new Discretionary Order with a new timestamp and with an increased size to include the unexecuted portions of the Discretionary IOC. The Exchange believes that the proposed rule change will benefit participants by enabling their Discretionary Orders to remain executable against new incoming liquidity when available liquidity within the discretionary price range is smaller than the full size of the Discretionary Order (provided that Participants have not specified a minimum quantity for execution).

The Exchange proposes to move existing rule text that governs the situations where more than one Order with Discretion satisfies conditions that would cause the generation of a Discretionary IOC simultaneously. Whereas now, in all such situations, the order in which such Discretionary IOCs are presented for execution is random, based on the respective processing time for each such Order; going forward, the system will present Discretionary IOCs associated with Discretionary Orders without Routing differently as it gains responsibility for handling such Orders from RASH. That is, the system will present multiple Discretionary IOCs associated with such Orders for execution in price-time priority, as is specified in Rule 3307(a). The price by which the Orders will be prioritized for execution refers to the price of the Discretionary IOCs that are generated, meaning the highest price for the Order with Discretion to buy (lowest price for the Order with Discretion to sell) within the discretionary price range. This change will not affect Discretionary Orders with Routing, when Discretionary IOCs are generated for routing, which will continue to be handled by RASH under the existing random presentment procedures.

The Exchange proposes to add to the Rule the following example to illustrate the new procedures. If a Participant enters a Price to Display Order to buy 500 shares at $11 with a discretionary price range of up to $11.03, then upon entry, the System will first execute the Order against any orders resting on the Exchange Book that are priced equal to or better than the limit price of the Discretionary Order. Assuming that no such resting order exists, the System will post the full size of the Price to Display Order to the Exchange Book in accordance with its parameters. If there is an Order on the Exchange Book to sell 200 shares priced at $11.03, the System will generate a Discretionary IOC to buy priced at $11.03 to execute against the Order on the Exchange Book, if an execution at $11.03 would not trade through a Protected Quotation; the remaining 300 shares of the original Order with Discretion will remain posted on the Exchange Book.[13]

With respect to procedures for processing Discretionary Orders with Routing Attributes assigned to them, the Exchange proposes to reorganize and consolidate the procedures, as well as to eliminate obsolete and duplicative text, and to improve readability.

Specifically, the Exchange proposes to largely delete bulleted text that presently describes distinct procedures for handling Discretionary Orders with passive and reactive routing strategies, as well as for handling Discretionary Orders with Routing Attributes depending upon whether the discretionary price range of the Order is pegged. The Exchange proposes to eliminate certain existing text that describes order handling procedures for Discretionary Orders with passive and reactive routing strategies after being posted because such procedures do not differ from the general procedures for handling Discretionary Orders with respect to available liquidity on the Exchange Book within the discretionary price range.[14] As to Discretionary Orders with reactive routing strategies, the Exchange believes that it is sufficient to state, going forward, that if

[12] A Discretionary IOC may not execute fully in a race condition where an incoming order executes against all or a portion of the available liquidity within the discretionary price range before the Discretionary IOC is able to do so.

[13] The Exchange also proposes to move and reorganize, but not substantively modify, certain text within Rule 3301B(g) to eliminate duplication and improve its readability.

[14] The Exchange proposes to retain the concept in the existing rule that whenever it generates a Discretionary IOC, the underlying Order with Discretion will be withheld or removed from the Exchange's Book and will then be routed and/or placed on the Exchange's Book if the Discretionary IOC does not exhaust the full size of the underlying Order with Discretion, with its price determined by the underlying Order Type and Order Attributes selected by the Participant. However, rather than applying this concept to all Discretionary Orders going forward, the proposal will apply it only to Discretionary Orders with Routing Attributes, as this is the context in which the concept applies, in practice.

a Discretionary IOC associated with such an Order does not exhaust the full size of the Discretionary Order, then the Exchange will generate and route additional Discretionary IOCs in response to new quotations within the discretionary price range according to the routing strategy assigned to the Order. Moreover, the Exchange proposes to retain language in the existing rule which states that, if a Discretionary Order uses a passive routing strategy, the System will not generate additional Discretionary IOC orders in response to new away market quotations within the discretionary price range unless the Order is updated in a manner that causes it to receive a new timestamp, in which case the Order will behave in the same manner as a newly entered Discretionary Order.

Moreover, the Exchange proposes to delete existing Rule text that describes how the Exchange handles Discretionary Orders with Routing Attributes in scenarios where such Orders do and do not have pegged discretionary price ranges associated with them. The text presently states that where a Discretionary IOC associated with such an Order does not exhaust the full size of the Order, the Exchange will post the remaining size of the Order to the Exchange Book in accordance with the parameters that apply to the underlying Order Type. With respect to Discretionary Orders with reactive routing strategies, the Exchange will examine whether there is an order on the Exchange Book or an accessible quotation at another trading venue that is within the discretionary price range and against which the Discretionary Order could execute. When the Exchange currently examines the Exchange Book in the scenario where the Discretionary Order with reactive routing has a pegged discretionary price range, it examines only displayed orders on the Exchange Book for this purpose, whereas if the Discretionary Order with Routing has no pegged discretionary price range, the Exchange examines all orders on its Book, including non-displayed orders. This distinction in order handling procedures is a legacy of the existing limitations of the RASH protocol that will no longer be applicable after the Exchange migrates responsibility from RASH to the System for handling Discretionary Orders. That is, going forward, the System will be capable of and will examine the Exchange Book for both displayed and non-displayed orders in the discretionary price range against which to execute Discretionary Orders with Routing, regardless of whether the discretionary price range of such Orders is pegged.

In the new proposed paragraph that governs Discretionary Orders with Routing, the Exchange also proposes to amend existing text concerning the price and size at which the Exchange will generate a Discretionary IOC when, before routing, it determines that there is liquidity available on the Exchange Book within the discretionary price range with which the Discretionary Orders may interact.[15] Whereas existing rule text states that the Exchange will generate a Discretionary IOC in this instance that matches the price and size of the Order on the Exchange Book, the proposed rule text states that the Exchange will generate a Discretionary IOC equal to the highest price for the Order with Discretion to buy (lowest price for the Order with Discretion to sell) within the discretionary price range and a size equal to the applicable size of the available liquidity on the Exchange Book.

Additionally in that same paragraph, the Exchange proposes to change existing language that governs the generation of a Discretionary IOC in response to accessible quotations within the discretionary price range at away market centers. The existing rule text states that the Exchange will generate a Discretionary IOC in this instance that matches the price and size of the away market quotation within the discretionary price range. The proposed rule, by contrast, states that the Exchange will generate one or more Discretionary IOCs that will match the price of the away market quotation. The size of the Discretionary IOC(s) generated in this instance will be determined by the router to maximize execution opportunities, consistent with existing routing strategies.

Last, as explained above, the Exchange proposes to move the following existing text to the new consolidated paragraph governing procedures for handling Discretionary Orders with Routing. The text clarifies that for these Orders (as opposed to Discretionary Orders without Routing), the existing practice of randomly presenting for execution simultaneously generated Discretionary IOCs for routing is still applicable; because responsibility for this functionality is still being managed by RASH, it will not be affected by the present system changes:

Furthermore, if a new quotation satisfies conditions that would cause the simultaneous generation of a Discretionary IOC for more than one Order with Discretion that have been assigned a Routing Order Attribute, the order in which such Discretionary IOCs are presented for execution is random, based on the respective processing time for each such Order.

The Exchange intends to implement the foregoing changes during the Fourth Quarter of 2021. The Exchange will issue an Equity Trader Alert at least 7 days in advance of implementing the changes.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Section 6(b)(5) of the Act,[17] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The Exchange believes that its proposed amendments to the Discretionary Order Attribute, at Rule 3301B(g), are consistent with the Act. The Exchange believes that its proposal to revise its process for handling Discretionary Orders so that they post to the Exchange Book, upon entry after checking for available interest at or better than their limit price, rather than attempt to execute against available liquidity within the discretionary price range immediately upon entry, will benefit Participants and investors because such immediate attempts at execution within the discretionary price range rarely succeed and typically result only in Discretionary Orders posting to the Book later than they would otherwise, and thus resulting in potentially lower queue priority. The proposed amendments will provide Participants with an opportunity to first secure queue priority by posting to the Book upon entry (after checking for available interest at or better than their limit price), and only generate a Discretionary IOC if and when the System later determines that liquidity within the discretionary price range is available for execution. The Exchange notes that it will still allow for Discretionary Orders to attempt to execute against available liquidity within the discretionary price range immediately upon entry if Participants select a Time-in-Force of Immediate-or-Cancel for such Orders.

[15] The Exchange notes that certain routing strategies, such as Directed Orders, do not check the Exchange system first before routing to other market centers.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

Additionally, the proposal to generate Discretionary IOCs that equal the size of available liquidity within the discretionary range, rather than the full size of Discretionary Orders, will benefit participants by enabling their Discretionary Orders to maintain their queue priority on the Exchange Book when available liquidity within the discretionary price range is smaller than the full size of the Discretionary Order.

The Exchange believes that it is consistent with the Act to amend the Rule to state that if the Discretionary IOC is not fully executed, the posted portion of the Discretionary Order will be reentered on the Exchange Book as a new Discretionary Order with a new timestamp and with an increased size to include the unexecuted portions of the Discretionary IOC. The Exchange believes that the proposed rule change will benefit participants by enabling their Discretionary Orders to remain executable against new incoming liquidity when available liquidity within the discretionary price range is smaller than the full size of the Discretionary Order (provided that Participants have not specified a minimum quantity for execution).

Furthermore, it is consistent with the Act to reorganize, consolidate, and otherwise amend the provisions of the existing Rule that describe procedures for handling Discretionary Orders with Routing Attributes, passive and reactive routing strategies, and pegged and non-pegged discretionary price ranges. The proposed changes will improve the clarity and readability of the Rule by eliminating unnecessary and duplicative text. It will also reflect an upgrade in the ability of the Exchange to examine its Book for both displayed and non-displayed orders against which a Discretionary Order with Routing and a pegged discretionary price range may execute (with such upgrade occurring as a product of responsibility for Discretionary Order handling migration from RASH to the Exchange's matching System). It also is consistent with the Act to clarify that for Discretionary Orders with Routing Attributes, the existing practice of randomly presenting for execution simultaneously generated Discretionary IOCs for routing still applies.

Likewise, it is consistent with the Act to modify the price at which the Exchange will generate Discretionary IOCs when, before routing a Discretionary Order with Routing, the Exchange determines that there is liquidity available on the Exchange Book within the discretionary price range with which the Discretionary Orders may interact. The current practice of generating a Discretionary IOC with a price equal to the price of the Order on the Exchange Book does not maximize the potential for executions, whereas, generating a Discretionary IOC with a price equal to the highest price for an Order to buy (lowest price for an Order to sell) within the discretionary price range allows the Discretionary IOC to access additional liquidity at a more aggressive price in the event of a race condition where the liquidity with which the Order with Discretion is reacting is removed before the Discretionary IOC is able to execute against it.

Finally, it is consistent with the Act to amend existing rule text to state that when the Exchange generates a Discretionary IOC to attempt to execute accessible liquidity within the discretionary price range at another market center, the Exchange will generate a Discretionary IOC that will match the price of the away market quotation, but the size will be determined by the router to maximize execution opportunities, consistent with existing routing strategies. The current rule, as written, does not contemplate the scenario where the remaining size of the Order with Routing is less than the size of the away market quotation; in which case a smaller order must be routed to the quoting market, comprising the full size of the Order with Routing. The new rule text allows for this behavior, and so more clearly communicates the operation of the System to Participants. Furthermore, additional non-displayed liquidity may exist on the quoting market in excess of the displayed size of the quote. It benefits the Participant to maximize execution opportunities for their orders, so the new rule text allows the router to send orders that are larger than the size of the away market quotation. Because an Order assigned both Discretion and Routing Order Attributes is withheld or removed from the Exchange Book whenever a Discretionary IOC is generated for routing, thereby yielding priority on the Exchange Book, there are no opportunity costs to routing additional shares in excess of the displayed quote.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that its proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. As a general principle, the proposed changes are reflective of the significant competition among Exchanges and non-exchange venues for order flow. In this regard, proposed changes that facilitate enhancements to the Exchange's System and order entry protocols as well as those that amend and clarify the Exchange's Rules regarding its Order Attributes, are pro-competitive because they bolster the efficiency, integrity, and overall attractiveness of the Exchange in an absolute sense and relative to its peers.

Moreover, none of the proposed changes will unduly burden intra-market competition among various Exchange participants. The Exchange's proposal to revise its processes for handling Discretionary Orders upon entry does have the potential to improve the relative queue positions of Discretionary Orders on the Exchange's Book, but these changes are warranted because existing processes are inefficient and result in opportunity costs to users of Discretionary Orders. Indeed, participants potentially lose queue priority when the System delays posting their Discretionary Orders to the Book only after making attempts to execute those Orders against liquidity within its discretionary price range immediately upon entry. Similarly, participants potentially lose queue priority whenever available liquidity within the discretionary price range is less than the size of a Discretionary Order, and the System processes residual shares by posting them to the Book with new timestamps.

Furthermore, routing orders to away markets for only the displayed size of their quotes unnecessarily limits the opportunity for execution against non-displayed liquidity, while restricting the price of a Discretionary IOC to the price of an available order on the Exchange Book (as opposed to assigning the most aggressive price allowed within the discretionary range) limits opportunities for execution when race conditions cause the original order that the Discretionary IOC was created to execute against to no longer be available by the time the Discretionary IOC is received by the System. The proposed changes have the potential to increase execution opportunities, but these changes are warranted because they will equally benefit all Exchange participants utilizing the Discretion Attribute by making the processes more efficient.

Likewise, there will be no adverse competitive impact from the Exchange's proposal to examine both displayed and non-displayed orders in the Exchange Book (as opposed to only displayed orders, in current practice) in the scenario where the Discretionary Order with reactive routing has a pegged discretionary price range. As explained

above, existing handling procedures in this scenario is a legacy of the limitations of the RASH protocol, which will no longer be applicable after the Exchange migrates responsibility from RASH to the System for handling Discretionary Orders.

For similar reasons, there will be no adverse competitive impact associated with the Exchange's proposal to present Discretionary IOCs associated with Discretionary Orders without Routing in price-time priority, rather than in random order, as is currently the case and as will remain the case for Discretionary IOCs associated with Discretionary Orders with Routing. Whereas RASH is unable to present Discretionary IOCs in time-price [sic] priority, the Exchange's system will be capable of doing so, and thus it will do so when it assumes responsibility for handling Discretionary Orders without routing. Insofar as RASH will continue to handle Discretionary Orders with Routing, existing randomized processes for presenting Discretionary IOCs associated with those Orders for routing will continue to apply.

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

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 [18] and Rule 19b–4(f)(6) thereunder.[19]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2021–67 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–Phlx–2021–67. 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–Phlx–2021–67 and should be submitted on or before November 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24165 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

[18] 15 U.S.C. 78s(b)(3)(A).

[19] 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 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. The Exchange has satisfied this requirement.

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–233, OMB Control No. 3235–0223]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 17f–2

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 350l *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 17f–2 (17 CFR 270.17f–2), entitled ''Custody of Investments by Registered Management Investment Company,'' establishes safeguards for arrangements in which a registered management investment company or business development company (''fund'') is deemed to maintain custody of its own assets, such as when the fund maintains its assets in a facility that provides safekeeping but not custodial services.[1] The rule includes four distinct requirements that are an information collection under the Paperwork Reduction Act. First, fund's directors must prepare a resolution designating not more than five fund officers or responsible employees who may have access to the fund's assets. Secondly, the fund's board must vote to approve this resolution. Third, the designated access persons (two or more of whom must act jointly when handling fund assets) must prepare a written notation providing certain information about each deposit or withdrawal of fund assets, and must transmit the notation to another officer or director designated by the directors. Lastly, an independent public

[1] The rule generally requires all assets to be deposited in the safekeeping of a ''bank or other company whose functions and physical facilities are supervised by Federal or State authority.''

accountant must verify the fund's assets three times each year, and two of those examinations must be unscheduled.[2]

Rule 17f–2's requirements are designed to safeguard fund assets from loss by requiring certain specific controls when those assets are not placed and maintained in the custody of a bank or other custodian as permitted under section 17(f) of the Investment Company Act of 1940 (15 U.S.C. 80a–17(f)) (''Act'') and the rules thereunder. Specifically, the requirement that directors designate access persons is intended to ensure that directors evaluate the trustworthiness of insiders who handle fund assets. The requirements that access persons act jointly in handling fund assets, prepare a written notation of each transaction, and transmit the notation to another designated person are intended to reduce the risk of misappropriation of fund assets by access persons, and to ensure that adequate records are prepared, reviewed by a responsible third person, and available for examination by the Commission. The requirement that auditors verify fund assets without notice twice each year is intended to provide an additional deterrent to the misappropriation of fund assets and to detect any irregularities. Less frequent examinations by a fund's accountants could impair the ability of the Commission's examination staff to ascertain the fund's compliance with the rule.

The Commission staff estimates that each fund makes 974 responses and spends an average of 252 hours annually in complying with the rule's requirements.[3] Commission staff estimates that on an annual basis it takes: (i) 0.5 hours of fund accounting personnel at a total cost of $111 and 1 hour of fund attorney personnel time at a cost of $425, for a total of 1.5 hours and a cost of $536 to draft director resolutions;[4] (ii) 0.5 hours of the fund's board of directors at a total cost of $2,385 to adopt the resolution;[5] (iii) 244 hours for the fund's accounting personnel at a total cost of $71,102 to prepare written notations of transactions;[6] and (iv) 3 hours for the fund's controller or administrator at a total cost of $1,494 to assist the independent public accountants when they perform verifications of fund assets.[7] The total of these four requirements would then be 249 hours at a cost of $75,517 per respondent. Commission staff estimates that approximately 183 funds file Form N–17f–2 each year.[8] Thus, the total annual hour burden for rule 17f–2 is estimated to be 45,384 hours.[9] Based on the total costs per fund listed above, the total cost of rule 17f–2's collection of information requirements is estimated to be approximately $13,819,611.[10]

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms. Complying with the collections of information required by rule 17f–2 is mandatory for those funds that maintain custody of their own assets. Responses will not be kept confidential. 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 control number.

The public may view background documentation for this information collection at the following website: >*www.reginfo.gov*<. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) >*www.reginfo.gov/public/do/PRAMain*< and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24136 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

[2] The accountant must transmit to the Commission promptly after each examination a certificate describing the examination on Form N–17f–2. The preparation and filing of Form N–17f–2, which largely serves as a cover-sheet for the accountant's certification of their audit, is covered by a separate information collection. The third (scheduled) examination may coincide with the annual verification required for every fund by section 30(g) of the Act (15 U.S.C. 80a–29(g)).

[3] The 974 responses are: 1 (one) response to draft and adopt the resolution and 973 notations. Estimates of the number of hours are based on conversations with individuals in the fund industry. The actual number of hours may vary significantly depending on individual fund assets.

[4] The estimate relating to fund accounting personnel is based on the following calculation: 0.5 (burden hours per fund) × $221 (senior accountant's hourly rate) = approximately $111. Unless otherwise indicated, the hourly wage figures used herein are from the Securities Industry and Financial Markets Association's Management & Professional Earnings in the Securities Industry 2013, modified by Commission staff to account for an 1800-hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead.

[5] The staff has estimated the average cost of board of director time as $4,770 per hour for the board as a whole, based on information received from funds and their counsel.

[6] Respondents estimated that each fund makes 973 responses on an annual basis and spends a total of 0.25 hours per response. The fund personnel involved are Accounts Payable Manager ($208 hourly rate), Operations Manager ($373 hourly rate) and Accounting Manager ($296 hourly rate). The average hourly rate of these personnel is approximately $292. The estimated cost of preparing notations is based on the following calculation: 974 × 0.25 × $292 = $71,102.

[7] This estimate is based on the following calculation: 3 × $498 (fund controller's hourly rate) = $1,494.

[8] On average, each year approximately 183 funds filed Form N–17f–2 with the Commission during calendar years 2018–2020. As every fund subject to rule 17f–2 must file Form N–17f–2, we believe this is a good estimate for the number of respondents to the rule.

[9] This estimate is based on the following calculation: 183 (funds) × 249 (total annual hourly burden per fund) = 45,384 hours for rule. The annual burden for rule 17f–2 does not include time spent preparing Form N–17f–2. The burden for Form N–17f–2 is included in a separate collection of information.

[10] This estimate is based on the following calculation: $75,517 (total annual cost per fund) × 183 funds = $13,819,611.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93488; File No. SR–NYSE–2021–44]

Self-Regulatory Organizations; New York Stock Exchange LLC, Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend Rules 7.31, 7.35, 7.35B, 7.35C, 98, and 104 Relating to the Closing Auction

November 1, 2021.

On September 3, 2021, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Rules 7.31 (Orders and Modifiers), 7.35 (General), 7.35B (DMM-Facilitated Closing Auctions), 7.35C (Exchange-Facilitated Auctions), 98 (Operation of a DMM Unit), and 104 (Dealings and Responsibilities of DMMs) relating to the Closing Auction. The proposed rule change was published for comment in the **Federal Register** on September 22, 2021.[3] The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 93037 (Sep. 16, 2021), 86 FR 52719 (Sep. 22, 2021) (SR–NYSE–2021–44).

Commission has received no comments on the proposed rule change.

Section 19(b)(2) of the Act[4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for the proposed rule change is November 6, 2021. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates December 21, 2021, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to approve or disapprove, the proposed rule change (File No. SR–NYSE–2021–44).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24166 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–253, OMB Control No. 3235–0260]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 23c–1

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 350l–3520), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 23c–1(a) under the Investment Company Act (17 CFR 270.23c–1(a)) permits a closed-end fund to repurchase its securities for cash if, in addition to the other requirements set forth in the rule, the following conditions are met: (i) Payment of the purchase price is accompanied or preceded by a written confirmation of the purchase (''written confirmation''); (ii) the asset coverage per unit of the security to be purchased is disclosed to the seller or his agent (''asset coverage disclosure''); and (iii) if the security is a stock, the fund has, within the preceding six months, informed stockholders of its intention to purchase stock (''six month notice''). Commission staff estimates that 56 closed-end funds undertake a total of 224 repurchases annually under rule 23c–1.[1] Staff estimates further that, with respect to each repurchase, each fund spends 2.5 hours to comply with the rule's written confirmation, asset coverage disclosure and six month notice requirements. Thus, Commission staff estimates the total annual respondent reporting burden is 560 hours.[2] Commission staff further estimates that the cost of the hourly burden per repurchase is approximately $330.50 (one half hour of a compliance attorney's time at $373 per hour,[3] and two hours of clerical time at $72 per hour[4]). The total annual cost for all funds is estimated to be $185,080.[5]

In addition, the fund must file with the Commission a copy of any written solicitation to purchase securities given by or on behalf of the fund to 10 or more persons. The copy must be filed as an exhibit to Form N–CSR (17 CFR 249.331and 274.128).[6] The burden associated with filing Form N–CSR is addressed in the submission related to that form.

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms.

Complying with the collection of information requirements of the rule is mandatory. The filings that the rule requires to be made with the Commission are available to the public. 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 control number.

The public may view background documentation for this information collection at the following website: >*www.reginfo.gov*<. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) >*www.reginfo.gov/public/do/PRAMain*< and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24143 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–289, OMB Control No. 3235–0327]

Proposed Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Form SE

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

[1] The number of closed-end funds that undertake repurchases annually under rule 23c–1 is based on information provided in response to Item C.7.i of Form N–CEN from January 1, 2020 through December 31, 2020.

[2] This estimate is based on the following calculation: 224 repurchases × 2.5 hours per repurchase = 560 hours.

[3] The $373/hour figure for a compliance attorney is from SIFMA's Management & Professional Earnings in the Securities Industry 2013, updated for 2021, modified by Commission staff to account for an 1800-hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead.

[4] The $72/hour figure for a compliance clerk is from SIFMA's Office Salaries in the Securities Industry 2013, updated for 2021, modified by Commission staff to account for an 1800-hour work-year and inflation, and multiplied by 2.93 to account for bonuses, firm size, employee benefits and overhead.

[5] This estimate is based on the following calculation: 560 repurchases × $330.5 per repurchase = $185,080.

[6] In addition, Item 9 of Form N–CSR requires closed-end funds to disclose information similar to the information that was required in Form N–23C–1, which was discontinued in 2004.

and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form SE (17 CFR 239.64) is used by registrants to file paper copies of exhibits, reports or other documents that would be difficult or impossible to submit electronically, as provided in Rule 311 of Regulation S–T (17 CFR 232.311). The information contained in Form SE is used by the Commission to identify paper copies of exhibits. Form SE is filed by individuals, companies or other entities that are required to file documents electronically. Approximately 19 registrants file Form SE and it takes an estimated 0.10 hours per response for a total annual burden of 2 hours (0.10 hours per response × 19 responses).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

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 control number.

Please direct your written comment to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24139 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93496; File No. SR–NYSE–2021–63]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List To Eliminate Expired and Obsolete Pillar Port Transition Fee Pricing

November 1, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on October 27, 2021, New York Stock Exchange LLC (''NYSE'' 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 its Price List to eliminate expired and obsolete Pillar port transition fee pricing. 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 purpose of this filing is to eliminate expired and obsolete Pillar port transition fee pricing now that there are no member organizations that did not complete the transition from older to newer and more efficient Pillar technology.

The Exchange proposes to implement these changes to its Price List effective October 27, 2021.

Background

Member organizations enter orders and order instructions, and receive information from the Exchange, by establishing a connection to a gateway that uses communication protocols that map to the order types and modifiers described in Exchange rules. These gateway connections, also known as logical port connections, are referred to as ''ports'' on the Exchange's Price List. Legacy ports connect with the Exchange via a Common Customer Gateway (known as ''CCG'') that accesses its equity trading systems (''Phase I ports''). Beginning July 1, 2019, the Exchange began making available ports using Pillar gateways to its member organizations (''Phase II ports'').

Effective July 3, 2019, the Exchange introduced transition pricing designed to provide member organizations an extended transition period to connect to the Exchange using Pillar technology with no fee increase. Specifically, the Exchange (1) adopted a cap on monthly fees for the use of certain ports connecting to the Exchange for the billing months July 2019 through March 2020 (the ''Transition Period''); (2) adopted a Decommission Extension Fee applicable for the billing months April 2020 through September 2020 (the ''Decommission Period'') for legacy port connections; and (3) prorated the monthly fee for certain ports activated after July 1, 2019, effective April 1, 2020.[4]

Effective March 2, 2020, the Exchange (1) extended the end of the Transition Period from March 2020 to August 2020 for member organizations to transition to the utilization of ports that connect to the Exchange using Pillar technology; (2) shortened the Decommission Period from six months (April 2020–September 2020) to four months (September–December 2020); (3) extended the

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 86360 (July 11, 2019), 84 FR 34210 (July 17, 2019) (SR–NYSE–2019–39).

effective date that the Exchange would prorate the monthly fee for certain ports activated on or after July 1, 2019 from April 1, 2020 to September 1, 2020; and (4) revised the fees charged for legacy port connections during the Decommission Period.[5]

Effective August 1, 2020, the Exchange (1) extended the end of the Transition Period from August 2020 to October 2020; (2) extended the beginning of the Decommission Period from September 2020 to November 2020 and the end of the Decommission Period from December 2020 to February 2021; and (3) extended the effective date that the Exchange would prorate the monthly fee for ports activated on or after July 1, 2019 from September 1, 2020 to November 1, 2020.[6]

Effective October 1, 2020, the Exchange (1) extended the end of the Transition Period from October 2020 to December 2020; (2) extended the beginning of the Decommission Period from November 2020 to January 2021 and the end of the Decommission Period from February 2021 to April 2021; and (3) extended the effective date that the Exchange would prorate the monthly fee for ports activated on or after July 1, 2019 from November 1, 2020 to January 1, 2021.[7]

Effective December 1, 2020, the Exchange (1) extended the end of the Transition Period from December 2020 to February 2021; (2) extended the beginning of the Decommission Period from January 2021 to March 2021 and the end of the Decommission Period from April 2021 to June 2021; and (3) extended the effective date that the Exchange would prorate the monthly fee for ports activated on or after July 1, 2019 from January 1, 2021 to March 1, 2021.[8]

Effective June 10, 2021, the Exchange extended the end of the Decommission Period two months from June 2021 to August 2021.[9]

Effective September 1, 2021, the Exchange extended the end of the Decommission Period one month from August 2021 to September 2021 in order to allow member organizations that did not complete the transition during the Transition Period the ability to choose to continue using Phase I ports until September 2021.[10]

The Decommission Period ended at the end of September 2021. There are no member organizations that did not complete the transition to Phase II ports during the Transition Period.

Proposed Rule Change

The Exchange proposes to delete Pillar port transition fee pricing (which is applicable to both order/quote entry and drop copy ports) in its entirety. Both the Transition Period and the Decommission Period have ended and, as noted above, there are no member organizations that did not complete the transition to Phase II ports during the Transition Period. Since the Exchange is no longer charging port transition fees, the Exchange proposes to delete the section of the Price List titled ''Pillar Port Transition Fee Pricing'' in its entirety as obsolete.

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any problems that member organizations would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[12] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Change Is Reasonable

The Exchange believes that the proposed elimination of Pillar port transition fees is reasonable because the fees are no longer being charged. The Exchange believes it is reasonable to delete obsolete fees from the Price List because it would streamline the Price List and reduce confusion as to which fees are applicable on the Exchange. The Exchange believes that amending the Price List to remove fees that are no longer charged would promote the protection of investors and the public interest because it would promote clarity and transparency in the Price List, thereby enabling market participants to navigate the Exchange's Price List more easily.

The Proposal Is an Equitable Allocation of Fees

The Exchange believes the proposal equitably allocates fees among its market participants because the obsolete port transition fees that the Exchange proposes to eliminate would be eliminated in their entirety, and would no longer be available to any member organization in any form. Similarly, the Exchange believes the proposal equitably allocates fees among its market participants because elimination of obsolete fees would apply to all similarly-situated member organizations on an equal basis. All such member organizations would continue to be subject to the same fee structure, and access to the Exchange's market would continue to be offered on fair and nondiscriminatory terms.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory because it neither targets nor will it have a disparate impact on any particular category of market participant. The Exchange believes that the proposal is not unfairly discriminatory because the proposed elimination of the obsolete fees would affect all similarly-situated market participants on an equal and non-discriminatory basis. The Exchange believes that eliminating obsolete fees would no longer be available to any member organization on an equal basis. The Exchange also believes that the proposed change would protect investors and the public interest because the deletion of obsolete fees would make the Price List more accessible and transparent and facilitate market participants' understanding of the fees charged for services currently offered by the Exchange.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[13] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance

[5] *See* Securities Exchange Act Release No. 88373 (March 12, 2020), 85 FR 15533 (March 18, 2020) (SR–NYSE–2020–14).

[6] *See* Securities Exchange Act Release No. 89591 (August 18, 2020), 85 FR 52159 (August 24, 2020) (SR–NYSE–2020–14).

[7] *See* Securities Exchange Act Release No. 90180 (October 14, 2020), 85 FR 66612 (October 20, 2020) (SR–NYSE–2020–82).

[8] *See* Securities Exchange Act Release No. 90661 (December 14, 2020), 85 FR 82532 (December 18, 2020) (SR–NYSE–2020–99).

[9] *See* Securities Exchange Act Release No. 92234 (June 22, 2021), 86 FR 34080 (June 28, 2021) (SR–NYSE–2021–36).

[10] *See* Securities Exchange Act Release No. 93001 (September 15, 2021), 86 FR 52530 (September 21, 2021) (SR–NYSE–2021–50).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4) & (5).

[13] 15 U.S.C. 78f(b)(8).

of the purposes of the Act. Instead, as discussed above, the proposal relates solely to elimination of an obsolete port transition fees and, as such, would not have any impact on intra- or inter-market competition because the proposed change is solely designed to accurately reflect the services that the Exchange currently offers, thereby adding clarity to the Price List.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [14] of the Act and subparagraph (f)(2) of Rule 19b–4 [15] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [16] 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–NYSE–2021–63 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–NYSE–2021–63. 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–NYSE–2021–63 and should be submitted on or before November 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24168 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(2).

[16] 15 U.S.C. 78s(b)(2)(B).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–421, OMB Control No. 3235–0481]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 15c2–8

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 15c2–8 (17 CFR 240.15c2–8). The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Rule 15c2–8 under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) requires broker-dealers to deliver preliminary and/or final prospectuses to certain people under certain circumstances. In connection with securities offerings generally, including initial public offerings (''IPOs''), the rule requires broker-dealers to take reasonable steps to distribute copies of the preliminary or final prospectus to anyone who makes a written request, as well as any broker-dealer who is expected to solicit purchases of the security and who makes a request. In connection with IPOs, the rule requires a broker-dealer to send a copy of the preliminary prospectus to any person who is expected to receive a confirmation of sale (generally, this means any person who is expected to actually purchase the security in the offering) at least 48 hours prior to the sending of such confirmation. This requirement is sometimes referred to as the ''48 hour rule.''

Additionally, managing underwriters are required to take reasonable steps to ensure that all broker-dealers participating in the distribution of or trading in the security have sufficient copies of the preliminary or final prospectus, as requested by them, to enable such broker-dealer to satisfy their respective prospectus delivery obligations pursuant to Rule 15c2–8, as well as Section 5 of the Securities Act of 1933.

Rule 15c2–8 implicitly requires that broker-dealers collect information, as such collection facilitates compliance with the rule. There is no requirement to submit collected information to the Commission. In order to comply with the rule, broker-dealers participating in a securities offering must keep accurate records of persons who have indicated interest in an IPO or requested a prospectus, so that they know to whom they must send a prospectus.

The Commission estimates that the time broker-dealers will spend complying with the collection of information required by the rule is 24,200 hours for equity IPOs and 29,320

hours for other offerings. The Commission estimates that the total annualized cost burden (copying and postage costs) is $48,400,000 for IPOs and $1,172,800 for other offerings.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24144 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–269, OMB Control No. 3235–0276]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Extension:
Rule 6c–7

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 6c–7 (17 CFR 270.6c–7) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) (''1940 Act'') provides exemption from certain provisions of Sections 22(e) and 27 of the 1940 Act for registered separate accounts offering variable annuity contracts to certain employees of Texas institutions of higher education participating in the Texas Optional Retirement Program. There are approximately 142 registrants governed by Rule 6c–7. The burden of compliance with Rule 6c–7, in connection with the registrants obtaining from a purchaser, prior to or at the time of purchase, a signed document acknowledging the restrictions on redeem ability imposed by Texas law, is estimated to be approximately 3 minutes per response for each of approximately 6,500 purchasers annually (at an estimated $72 per hour),[1] for a total annual burden of 325 hours (at a total annual cost of $23,400).

Rule 6c–7 requires that the separate account's registration statement under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) include a representation that Rule 6c–7 is being relied upon and is being complied with. This requirement enhances the Commission's ability to monitor utilization of and compliance with the rule. There are no recordkeeping requirements with respect to Rule 6c–7.

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules or forms. The Commission does not include in the estimate of average burden hours the time preparing registration statements and sales literature disclosure regarding the restrictions on redeem ability imposed by Texas law. The estimate of burden hours for completing the relevant registration statements are reported on the separate PRA submissions for those statements. (See the separate PRA submissions for Form N–3 (17 CFR 274.11b) and Form N–4 (17 CFR 274.11c).

Complying with the collection of information requirements of the rules is necessary to obtain a benefit. 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 control number.

The public may view background documentation for this information collection at the following website: >*www.reginfo.gov*<. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) >*www.reginfo.gov/public/do/PRAMain*< and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24146 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

[1] $72/hour figure for a Compliance Clerk is based on the Commission's estimates concerning the allocation of burden hours and the relevant wage rates from the Commission's consultations with industry representatives and on salary information for the securities industry compiled by the Securities Industry and Financial Markets Association's Office Salaries in the Securities Industry 2013. The estimated wage figures are modified by Commission staff to account for an 1,800-hour work-year and multiplied by 2.93 to account for bonuses, firm size, employee benefits, overhead, and adjusted to account for the effects of inflation. *See* Securities Industry and Financial Markets Association, Report on Management & Professional Earnings in the Securities Industry 2013.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93501; File No. S7–13–12]

Order Granting Conditional Exemptions Under the Securities Exchange Act of 1934 in Connection With the Portfolio Margining of Cleared Swaps and Security-Based Swaps That Are Credit Default Swaps

November 1, 2021.

AGENCY: Securities and Exchange Commission (''SEC'' or ''Commission'').

ACTION: Exemptive order.

SUMMARY: The Commission is granting exemptive relief, subject to certain conditions, from compliance with certain provisions of the Securities Exchange Act of 1934 in connection with a program to portfolio margin cleared swaps customer and affiliate positions in cleared credit default swaps that are swaps and security-based swaps in a segregated account established and maintained in accordance with Section 4d(f) of the Commodity Exchange Act (in the case of a cleared swaps customer) or a cleared swaps proprietary account (in the case of an affiliate). This exemptive relief supersedes and replaces the

Commission's *Order Granting Conditional Exemptions under the Securities Exchange Act of 1934 in Connection with Portfolio Margining of Swaps and Security-based Swaps* issued in December 2012.

DATES: This order is effective November 1, 2021.

FOR FURTHER INFORMATION CONTACT: Michael A. Macchiaroli, Associate Director, at (202) 551–5525; Thomas K. McGowan, Associate Director, at (202) 551–5521; Randall W. Roy, Deputy Associate Director, at (202) 551–5522; Raymond Lombardo, Assistant Director, at 202–551–5755; or Sheila Dombal Swartz, Senior Special Counsel, at (202) 551–5545, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–7010.

I. Introduction

The Commission, by order, is granting conditional exemptive relief to SEC-registered clearing agencies also registered with the Commodity Futures Trading Commission (''CFTC'') as derivative clearing organizations (''clearing agency/DCOs'') and SEC-registered broker-dealers also registered with the CFTC as futures commission merchants (''BD/FCMs''). This order (''2021 Final Order'') exempts these entities from compliance with certain provisions of the Securities Exchange Act of 1934 (''Exchange Act'') in connection with a program to portfolio margin cleared swaps customer and affiliate positions in cleared security-based swaps and swaps that are credit default swaps (''CDS'') in a segregated account established and maintained in accordance with Section 4d(f) of the Commodity Exchange Act (''CEA'') in the case of a cleared swaps customer (''CFTC cleared swaps customer account'') or a cleared swaps proprietary account in the case of an affiliate (''CFTC cleared swaps proprietary account'') (each a ''CFTC cleared swaps account''), and to calculate margin requirements on a portfolio basis.

The 2021 Final Order supersedes and replaces the Commission's December 2012 order providing similar relief (''2012 Order''), and modifies certain of its conditions, as discussed in more detail below.[1] In particular, the 2021 Final Order eliminates conditions (a)(1) and (a)(2) in the 2012 Order pertaining to the exemptions for clearing agency/DCOs.[2] The requirements to adhere to the 2012 Order's conditions were designed to be triggered on the compliance date for the final capital, margin, and segregation requirements for security-based swap dealers (''SBSDs''): October 6, 2021. Conditions (a)(1) and (a)(2) in the 2012 Order were intended to provide an option for security-based swap customers to portfolio margin cleared security-based swaps and swaps that are CDS (''cleared CDS'') in a security-based swap account in accordance with Section 3E of the Exchange Act (''SEC SBS account'') as an alternative to a CFTC cleared swaps account.[3]

The 2021 Final Order also modifies the conditions in paragraphs (b)(1)(ii) and (2)(ii) of the 2012 Order requiring subordination agreements. The modifications provide that the scope of the subordination only extends to money, securities, or other property held in the subordinating person's CFTC cleared customer or proprietary account. The modifications also provide that the person need not subordinate claims to money, securities, or other property held in the subordinating person's CFTC cleared customer or proprietary account to the claims of general creditors.

In addition, the 2021 Final Order eliminates condition (b)(3) in the 2012 Order, which required approval of a BD/FCM's margin methodology by the Commission or Commission staff. Instead, under the 2021 Final Order, a BD/FCM must have an internal risk management program that has been approved in advance by the Commission or the Commission staff. Further, under the 2021 Final Order, the internal risk management program must have certain standards drawn from the letters the staff of the Division of Trading and Markets (''Division staff'') issued to BD/FCMs to approve their margin methodologies pursuant to the 2012 Order.[4] These staff letters will be withdrawn. The 2021 Final Order provides that any BD/FCM that received a staff letter approving its margin methodology prior to the issuance of the 2021 Final Order is deemed to have an approved internal risk management program for the purposes of the 2021 Final Order.

II. Background

A. 2012 Order

On December 14, 2012, the Commission issued the 2012 Order to provide relief so that clearing agency/DCOs and BD/FCMs could offer customers portfolio margining of cleared CDS in a CFTC cleared swaps account (''CDS portfolio margin program'').[5] The 2012 Order exempts a clearing agency/DCO from Sections 3E(b), 3E(d) and 3E(e) of the Exchange Act and any rules thereunder, solely to perform the functions of a clearing agency/DCO under the CDS portfolio margin program, subject to five conditions.[6] It further exempts a BD/FCM from Sections 3E(b), 3E(d), 3E(e), and 15(c)(3) of the Exchange Act, and Rule 15c3–3, as well as from any requirement to treat an affiliate (as defined in association with the ''cleared swaps proprietary account'' definition in CFTC Rule 22.1) as a customer for purposes of Rules 8c–1 and 15c2–1, subject to six conditions.[7] The conditions applicable to clearing agency/DCOs and BD/FCMs were designed to: (1) Protect money, securities, and property of security-based swap customers; (2) address certain differences in the statutory requirements of the Exchange Act and

[1] *Order Granting Conditional Exemptions under the Securities Exchange Act of 1934 in Connection with Portfolio Margining of Swaps and Security-based Swaps,* Exchange Act Release No. 68433 (Dec. 12, 2012) 77 FR 75211 (Dec. 19, 2012).

[2] *See* 2012 Order, 77 FR 75219–20.

[3] The Commission has adopted capital, margin, and segregation requirements under the Exchange Act for security-based swaps dealers (''SBSDs''). *See Capital, Margin, and Segregation Requirements for Security-Based Swap Dealers and Major Security-Based Swap Participants and Capital and Segregation Requirements for Broker-Dealers,* Exchange Act Release No. 86175 (June 21, 2019), 84 FR 43872, 43956–57 (Aug. 22, 2019) (''Capital, Margin, and Segregation Adopting Release'').

[4] The staff letters are available at *https://www.sec.gov/rules/exorders/exordersarchive/exorders2012.shtml.*

[5] The CFTC also issued a companion exemptive order on January 13, 2013 permitting ICE Clear Credit and its BD/FCM clearing members to provide for the portfolio margining of cleared swaps and security-based swaps that are CDS. *See* CFTC, *Order, Treatment of Funds Held in Connection with Clearing by ICE Clear Credit of Credit Default Swaps* (Jan. 13, 2013) (''2013 CFTC Portfolio Margin Order''), *available at https://www.cftc.gov/sites/default/files/idc/groups/public/@newsroom/documents/file/icecreditclearorder011413.pdf. See also* CFTC, *Order, Treatment of Funds Held in Connection with Clearing by ICE Clear Europe of Credit Default Swaps* (Apr. 9, 2013), *available at https://www.cftc.gov/sites/default/files/stellent/groups/public/@requestsandactions/documents/ifdocs/iceclearеurope4dfcds040913.pdf.*

[6] *See* 2012 Order, 77 FR 75215–16 (discussing five clearing agency/DCO conditions).

[7] *See* 2012 Order, 77 FR 75213–14 (discussing these sections of the Exchange Act and the rules), 75216–19 (discussing the conditions), and 75220–21 (setting forth the conditions). *See also Order Granting Exemptions from Sections 8 and 15(a)(1) of the Securities Exchange Act of 1934 and Rules 3b–13(b)(2), 8c–1, 10b–10, 15a–1(c), 15a–1(d) and 15c2–1 Thereunder in Connection with the Revision of the Definition of ''Security'' to Encompass Security-Based Swaps and Determining the Expiration Date for a Temporary Exemption from Section 29(b) of the Securities Exchange Act of 1934 in Connection with Registration of Security-Based Swap Dealers and Major Security-Based Swap Participants,* Exchange Act Release No. 90308 (Nov. 2, 2020), 85 FR 70667 (Nov. 5, 2020) (providing exemptions from certain rules including Rules 8c–1 and 15c–1 in connection with the revision of the Exchange Act definition of ''security'' to encompass security-based swaps).

the CEA; and (3) promote appropriate risk management and disclosure.[8]

B. Division Staff Letters

On March 8, 2013, the Division staff issued temporary conditional approval letters to seven BD/FCMs pursuant to condition (b)(3) in the 2012 Order[9] permitting them to participate in the CDS portfolio margin program, subject to certain conditions (the ''March 8, 2013 letters'').[10] The conditions included a requirement to collect initial margin based on a multiplier of the clearing agency/DCO margin requirement or to take a 100% capital charge for the difference.

On June 7, 2013, the Division staff issued updated temporary conditional letters to the seven BD/FCMs that received the March 8, 2013 letters, and to one additional BD/FCM, setting forth revised conditions for participation in the CDS portfolio margin program (''the June 7, 2013 letters''). The relief given by the June 7, 2013 letters was conditioned on the BD/FCMs implementing a margin regime and establishing minimum risk management standards by December 7, 2013. On December 6, 2013, the Division staff issued letters to the BD/FCMs extending the December 7, 2013 date to January 31, 2014. On January 31, 2014, the Division staff issued letters to the eight BD/FCMs permanently approving their margin methodologies, subject to the conditions in the June 7, 2013 letters (''January 31, 2014 letters''). Subsequent to the issuance of the January 31, 2014 letters, the Division staff approved the margin methodologies of two additional BD/FCMs, subject to the conditions in the June 7, 2013 letters.[11] All the letters referenced above will be withdrawn. The 2021 Final Order requires that the BD/FCMs have an approved internal risk management program. Pursuant to the 2021 Final Order, all BD/FCMs that received a letter approving their margin methodologies will be deemed to have an approved internal risk management program.

C. Previous Request for Comment

In October 2020, the Commission published a proposed order that would modify conditions in the 2012 Order and supersede and replace the 2012 Order (''2020 Proposed Order'').[12] The Commission received comments on the 2020 Proposed Order.[13] Commenters generally supported the Commission's approach and offered some suggested modifications.[14] One commenter stated market participants have confidence in the current structure, including the 2012 Order, which has allowed increased innovation in the cleared CDS products and increased voluntary clearing of security-based swaps.[15] Further, commenters supported the Commission's approach of seeking to preserve the status quo while making changes to further enhance the efficient operation of the cleared CDS market.[16] The comments and the Commission's response to them are discussed in detail below.

III. Discussion

Since the issuance of the 2012 Order, the SEC staff has monitored the operations of the BD/FCMs participating in the CDS portfolio margin program as well as the market for cleared CDS. The Commission is issuing this 2021 Final Order with modified conditions in light of: (1) The experience gained from this monitoring; and (2) comment letters addressing portfolio margining received in response to the 2012 Order, the 2020 Proposed Order, and in the context of the SEC's recently finalized rulemaking adopting capital, margin and segregation requirements for SBSDs.[17] This 2021 Final Order also is in response to the CFTC initiating mandatory clearing of certain swaps, including broad-based index CDS.[18] The following discussion describes the conditions of the 2021 Final Order—many of which are largely consistent with conditions in the 2012 Order. Modifications to the conditions in the 2012 Order are discussed below.

A. Conditions for Clearing Agency/DCOs

1. Elimination of Conditions Relating To Expanding the CDS Portfolio Margin Program to Securities Accounts

The conditions in paragraphs (a)(1) and (a)(2) of the 2012 Order were intended to provide customers the option to portfolio margin cleared CDS in an SEC SBS account once the SEC's margin and segregation rules for SBSDs are in place.[19] In particular, paragraph (a)(1) required that the clearing agency/DCO, by the later of six months after the adoption date of the final margin and segregation rules for security-based swaps or the compliance date of such rules, to take all necessary action within its control to *obtain any relief needed* to permit its BD/FCM clearing members to maintain customer money, securities, and property received by the BD/FCM to margin, guarantee, or secure customer positions in cleared CDS in an SEC SBS account for the purpose of the CDS portfolio margin program. Paragraph (a)(2) required the clearing agency/DCO, within the same timeframe, to take all necessary action within its control, to *establish rules and operational practices* to permit its BD/FCM clearing members to maintain customer money, securities, and property received by the BD/FCM to margin, guarantee, or secure customer positions in cleared CDS in an SEC SBS account for the purpose of the CDS portfolio margin program. Thus, the requirements to adhere to conditions in paragraphs (a)(1) and (2) of the 2012 Order were triggered on the compliance date for the final capital, margin, and segregation requirements for SBSDs: October 6, 2021.

[8] *See* 2012 Order, 77 FR 75214. The 2012 Order also sought comment on all aspects of the exemptions it provided. 77 FR 75219. Letters responding to this request for comment are available at *https://www.sec.gov/comments/s7-13-12/s71312.shtml.*

[9] *See* 2012 Order, 77 FR 75220 (providing that BD/FCM must require minimum margin levels with respect to any customer transaction in a program to commingle and portfolio margin CDS at least equal to the amount determined using a margin methodology established and maintained by the BD/FCM that has been approved by the Commission or the Commission staff).

[10] The March 8, 2013 letters and other staff letters to the BD/FCMs discussed in this 2021 Final Order are available at: *https://www.sec.gov/rules/exorders/exordersarchive/exorders2012.shtml.*

[11] The Division staff also issued an additional letter relating to the transfer of a CDS portfolio margin program using the same internal risk model and same internal risk management system from one broker-dealer affiliate to another. The June 7, 2013 letters and subsequent staff letters are collectively referred to below as the ''BD/FCM staff letters.''

[12] *See Proposed Order Granting Conditional Exemptions Under the Securities Exchange Act of 1934 in Connection With the Portfolio Margining of Swaps and Security-Based Swaps That Are Credit Default Swaps,* Exchange Act Release No. 90276 (Oct. 28, 2020), 85 FR 70657 (Nov. 5, 2020).

[13] The comments are available at *https://www.sec.gov/comments/s7-13-12/s71312.htm.*

[14] *See* Letter from Chris Edmonds, Global Head of Clearing and Risk, Intercontinental Exchange, Inc. (Dec. 7, 2020) (''ICE Letter''); Letter from Allison Lurton, General Counsel and Chief Legal Officer, Futures Industry Association (Dec. 7, 2020) (''FIA Letter''); Letter from Jason Silverstein, Esq., Managing Director and Associate General Counsel, SIFMA Asset Management Group, Jennifer W. Han, Managing Director & Counsel, Regulatory Affairs, Managed Funds Association (Dec. 7, 2020) (''SIFMA AMG/MFA Letter''); and Letter from Sarah Bessin, Associate General Counsel, Investment Company Institute (Dec. 7, 2020) (''ICI Letter'').

[15] ICE Letter.

[16] FIA Letter; SIFMA AMG/MFA Letter.

[17] The comment letters received with respect to this rulemaking are available at *https://www.sec.gov/comments/s7-08-12/s70812.shtml.*

[18] *See, e.g., CFTC Announces that Mandatory Clearing Begins Today,* CFTC Press Release No. 6529–13 (Mar. 11, 2013) (announcing that swap dealers, major swap participants and private funds active in the swaps market are required to begin clearing certain index CDS); *CFTC Announces that Mandatory Clearing for Category 2 Entities Begins Today,* CFTC Press Release No. 6607–13 (June 13, 2013) (announcing the second phase of required clearing for certain CDS and interest rate swaps).

[19] *See* 2012 Order, 77 FR 75215–16 (discussing the conditions) and 75219–20 (setting forth the conditions).

In the 2012 Order, the Commission stated that it was important to ultimately provide market participants with the ability to select an account structure to manage their individual risks by taking into account the different regulatory provisions that may apply to different account types and any costs incurred.[20] Market participants have been clearing CDS under the CDS portfolio margin program since the initial BD/FCM staff letters were issued in 2013. The CDS portfolio margining program has allowed greater efficiencies in clearing, allowing the offset of positions and the ability to margin cleared CDS in a single account. Portfolio margining facilitates margin requirements that better reflect the overall risks presented by a CDS portfolio, which may result in decreased margin costs. Because of these greater efficiencies and potential cost reductions available under the current CDS portfolio margin program in a CFTC cleared swaps account, market participants have not expressed a desire to portfolio margin cleared CDS in an SEC SBS account. This lack of market interest in a securities account alternative also is consistent with: (1) The comments of ICE Clear Credit in 2011 that it received no indication in its discussions with market participants that they desired a securities account option with respect to its petition for rulemaking to portfolio margin cleared CDS; and (2) the Division staff's experience in monitoring the CDS portfolio margin program. In the 2020 Proposed Order, therefore, the Commission preliminarily believed that it may be appropriate to eliminate the SEC SBS account conditions.[21]

Commenters supported the Commission's proposal in the 2020 Proposed Order to eliminate the clearing agency/DCO conditions relating to expanding the CDS portfolio margin program to SEC SBS accounts and generally agreed there is a lack of market interest in a securities account alternative.[22] One commenter stated that the current cleared CDS portfolio margining structure is operating effectively and efficiently and that there has been no expressed interest by market participants to undertake the material additional costs and risky operational changes to expand the portfolio margining to SEC SBS accounts.[23] This commenter also stated that requiring a securities account alternative would lead to material modifications to existing systems and create unnecessary duplicative processes.[24] Another commenter stated that the program has been effective in accommodating the portfolio margining needs of market participants who must react quickly to dynamic market conditions, risk management and hedging requirements, and evolving portfolio compositions.[25] This commenter stated that it is critical the Commission remain cognizant of the significant time and expense BD/FCMs, their customers, and the clearinghouses have already invested towards creating a safe and attractive model for the clearing of all CDS.[26] Finally, one commenter in supporting the elimination of the securities account alternative stated that regulated funds typically do not engage in portfolio margining in a securities account or a security-based swap account.[27]

Portfolio margining cleared CDS in an SEC SBS account also would provide greater efficiencies and cost reductions. However, the Commission is eliminating these conditions because of the success of the current CDS portfolio margin program, the confirmed lack of market interest in a securities account alternative, and the comments supporting their elimination.[28] Their removal, however, will not prohibit a clearing agency/DCO from offering an SEC SBS account option in the future, if market conditions change and the demand arises, subject to applicable regulatory approvals and relief.

Further, in connection with the elimination of conditions related to the SEC SBS account alternative, commenters asked the Commission to clarify whether single-name CDS may always be cleared through a CFTC cleared swaps account subject to the margin and risk management regime in the 2020 Proposed Order.[29] One commenter stated that it is not aware of any clearing agency/DCO that offers a securities account option. Consequently, this commenter stated that the cleared swaps account is the only currently available option to clear single-name CDS.[30] In response to these comments, single-name CDS that are held in a CFTC cleared swaps account and not part of a CDS portfolio margin program (*i.e.,* an account at a BD/FCM that holds at all times only single-name CDS positions) would be outside the scope of this 2021 Final Order. The exemptive relief in 2021 Final Order is conditioned on the requirement that cleared CDS that are security-based swaps and included in a CFTC cleared swaps account must be part of a CDS portfolio margin program. Clearing solely single-name CDS in a cleared CFTC swaps account without the inclusion of cleared swaps that are CDS at any point in time would not be considered a CDS portfolio margin program. For example, a CFTC cleared swaps account that is part of a CDS portfolio margin program that holds at various times both single-name and index CDS positions is subject to the conditions of this 2021 Final Order. Consequently, the 2021 Final Order only applies to cleared CDS, including single-name and index CDS, that are part of a CDS portfolio margin program. Finally, in response to the comment that a cleared swaps account is the only currently available option to clear single-name CDS, under the Commission's new segregation rules for security-based swap activities, a clearing agency/DCO could offer an SEC SBS account option to market participants to clear single-name CDS that are not part of a CDS portfolio margin program.[31]

2. Conditions

The three clearing agency/DCO conditions in the 2020 Proposed Order are largely consistent with the conditions in paragraphs (a)(3), (4), and (5) of the 2012 Order, respectively.[32] One commenter supported retaining these conditions and stated they largely maintain the well understood status quo with the 2012 Order.[33] This commenter also stated that the existing portfolio margining structure for cleared CDS instruments has operated safely, effectively and efficiently and, accordingly, it is in agreement with the Commission's efforts to uphold the current model.[34] The Commission agrees with the commenter and is adopting the three clearing agency/DCO conditions as proposed in the 2020 Proposed Order.[35]

[20] *See* 77 FR 75216.

[21] *See* 2020 Proposed Order, 85 FR 70659–60.

[22] *See* ICE Letter; FIA Letter; SIFMA AMG/MFA Letter; ICI Letter.

[23] ICE Letter.

[24] ICE Letter.

[25] FIA Letter.

[26] FIA Letter.

[27] ICI Letter.

[28] *See* 2021 Final Order, ¶ (a).

[29] FIA Letter; SIFMA AMG/MFA Letter.

[30] SIFMA AMG/MFA Letter.

[31] *See* paragraph (p) of Rule 15c3–3 (segregation requirements for security-based swaps). 17 CFR 240.15c3–3(p).

[32] *See* 2020 Proposed Order, 85 FR 70660 (discussing the conditions) and 70665 (setting forth the conditions); *see also* 2012 Order, 77 FR 75216 (discussing the conditions) and 75220 (setting forth the conditions).

[33] ICE Letter.

[34] ICE Letter.

[35] *See* 2021 Final Order, ¶¶ (a)(1), (2), and (3). The Commission made some technical changes to the DCO/clearing agency conditions in the 2021 Final Order to account for the elimination of conditions (a)(1) and (2) from the 2012 Order. These changes

The first condition requires the clearing agency/DCO to obtain any other relief needed to permit a BD/FCM to maintain cleared swaps customer or affiliate money, securities, and property received to margin, guarantee, or secure cleared swaps customer or affiliate positions in cleared CDS in a CFTC cleared swaps customer account or a CFTC cleared swaps proprietary account, respectively, for the purpose of clearing such cleared swaps customer or affiliate positions under the CDS portfolio margin program.[36] This condition is designed to help ensure that the exemption applies only in circumstances where the regulatory framework under the CEA and the CFTC's rules is applicable.

The second clearing agency/DCO condition requires the organization to have appropriate rules and operational practices to permit a BD/FCM to maintain cleared swaps customer or affiliate money, securities, and property received to margin, guarantee, or secure cleared swaps customer or affiliate positions in cleared CDS in a CFTC cleared swaps customer account or a cleared swaps proprietary account, respectively, for the purpose of clearing such cleared swaps customer or affiliate positions under the CDS portfolio margin program.[37] This condition also is designed to help ensure the exemption applies only in circumstances where the regulatory framework under the CEA and the CFTC's rules is applicable.

The third clearing agency/DCO condition requires the organization to have rules mandating that each cleared swaps customer and affiliate of the BD/FCM participating in the CDS portfolio margin program must be an ''eligible contract participant'' as defined in Section 1a(18) of the CEA.[38] Given that Congress determined it is appropriate to include these limitations in the Dodd-Frank Act with respect to eligible contract participants, it is appropriate to limit the exemptions in the 2021 Final Order to cleared CDS entered into with eligible contract participants.[39]

B. Conditions for BD/FCMs

The first, second, fourth, fifth, and sixth BD/FCM conditions in the 2020 Proposed Order were generally consistent with the conditions in paragraphs (b)(1), (2), (4), (5) and (6) of the 2012 Order, respectively.[40] As discussed below, the Commission is adopting them in the 2021 Final Order substantially as proposed in the 2020 Proposed Order.[41]

The first BD/FCM condition consists of two requirements and applies with respect to transactions involving persons that *are not affiliates* of the BD/FCM (*i.e.,* cleared swaps customers).[42] The Commission received no comments on the first requirement and is adopting it as proposed in the 2020 Proposed Order.[43] Under this requirement, the BD/FCM must maintain cleared swaps customer money, securities, and property received to margin, guarantee or secure cleared swaps customer positions consisting of cleared CDS in a CFTC cleared swaps customer account established and maintained for the purpose of the CDS portfolio margin program. This condition is designed to help ensure that—in the absence of the security-based swap and securities customer protections afforded by the securities laws—collateral in the account is subject to the protections afforded by an alternative regulatory scheme (*i.e.,* the CEA and the CFTC's rules). The intent is to avoid having the assets in the account fall into a regulatory gap in which neither the federal securities laws nor the federal commodity futures laws apply. The condition also is designed to limit the relief to accounts that are established and maintained specifically for the purpose of the CDS portfolio margin program.

As discussed below, the Commission received comments on the second requirement in the 2020 Proposed Order and, in response, is modifying it.[44] Under this requirement in the 2020 Proposed Order, the BD/FCM needed to enter into a non-conforming subordination agreement with each non-affiliated cleared swaps customer that covers the customer's money, securities, or property held in a CFTC cleared swaps customer account.[45] As proposed, the non-conforming subordination agreement needed to contain: (1) A specific acknowledgment by the cleared swaps customer that money, securities or property held in a CFTC cleared swaps customer account will not receive customer treatment under the Exchange Act or Securities Investor Protection Act of 1970 (''SIPA'') or be treated as ''customer property'' as defined in 11 U.S.C. 741 in a liquidation of the BD/FCM (''stockbroker liquidation''), and that such money, securities or property will be subject to any applicable protections under Subchapter IV of Chapter 7 of Title 11 of the United States Code and rules and regulations thereunder (''commodity broker liquidation provisions''); and (2) an affirmation by the cleared swaps customer that claims to ''customer property'' as defined in SIPA or 11 U.S.C. 741 against the BD/FCM will be subordinated to the claims of securities

include re-numbering the remaining clearing agency/DCO conditions and moving the definition of ''BD/FCM'' from condition (a)(1) in the 2012 Order (which would be eliminated) to condition (a)(1) in the proposed order (which parallels condition (a)(3) in the 2012 Order). Finally, the Commission is replacing the term ''shall'' in two places with the term ''will'' and ''must,'' respectively. No comments were received on these changes and the Commission is adopting them as proposed in the 2020 Proposed Order.

[36] *See* 2021 Final Order, ¶ (a)(1). The 2021 Final Order also eliminates use of the generic term ''customer'' in the 2012 Order and instead use the more specific terms ''cleared swaps customer,'' ''affiliate,'' ''security-based swap customer,'' and ''securities customer''. In addition, the 2021 Final Order adds specific language to clarify that cleared CDS positions of cleared swaps customers are held in CFTC cleared swaps customer accounts and affiliate positions are held in CFTC cleared swaps proprietary accounts. These changes reflect the different treatment each type of person and account would receive under the CEA and rules thereunder, and applicable bankruptcy laws. No comments were received on these changes and the Commission is adopting them as proposed in the 2020 Proposed Order.

[37] *See* 2021 Final Order, ¶ (a)(2).

[38] *See* 2021 Final Order, ¶ (a)(3). The 2012 Order provided that each ''customer'' must be an eligible contract participant. 77 FR 75220.

[39] The Dodd-Frank Act limits the swaps and security-based swaps transactions that may be entered into by parties that are not eligible contract participants. For example, under Section 6(l) of the Exchange Act, only an eligible contract participant may enter into security-based swaps that are not effected on a national securities exchange. 15 U.S.C. 78f(l). In addition, security-based swaps that are not registered pursuant to the Securities Act of 1933 (''Securities Act'') can only be sold to eligible contract participants. 15 U.S.C. 77e(e). Section 5(e) of the Securities Act specifically provides that it shall be unlawful to for any person, directly or indirectly, to make use of any means or instruments of transportation or communication in interstate commerce or of the mails to offer to sell, offer to buy or purchase or sell a security-based swap to any person who is not an eligible contract participant, unless the transaction is registered under the Securities Act. *Id. See also* 2020 Proposed Order, 85 FR 70660.

[40] *See* 2020 Proposed Order at 85 FR 70660–64 (discussing the conditions) and 70665–66 (setting forth the conditions); *see also* 2012 Order, 77 FR 75216–19 (discussing the conditions) and 75220–21 (setting forth the conditions). The Commission made some technical and stylistic changes to these conditions, including replacing the term ''shall'' with ''must'' and capitalizing the first letter in each of the conditions (and their subparagraphs). Finally, the Commission inserted the phrase ''Section 8 of the Exchange Act and'' before ''Exchange Act Rules 8c–1 and 15c2–1'' in paragraph (b) of the 2020 Proposed Order to be consistent with the other rule references in the order, which refer to the relevant statute. No comments were received on these changes and the Commission is adopting them as proposed in the 2020 Proposed Order.

[41] *See* 2021 Final Order, ¶¶ (b)(1), (2), (4), (5), and (6).

[42] *See* 2021 Final Order, ¶ (b)(1).

[43] *See* 2021 Final Order, ¶ (b)(1)(i); *see also* 2020 Proposed Order, 85 FR 70660.

[44] *See* 2020 Proposed Order, 85 FR 70660–61 (discussing the condition) and 70666 (setting forth the condition).

[45] *Id.*

customers and security-based swap customers.

The 2012 Order required an affirmation by the customer that all of its claims with respect to money, securities, or property held in the CDS portfolio margin account against the BD/FCM will be subordinated to the claims of other securities customers and security-based swap customers not participating in the CDS portfolio margin program.[46] To better clarify that the cleared swaps customer is not subordinating claims to general creditors, the Commission modified condition (b)(1)(ii) of the 2012 Order, as stated above, in the 2020 Proposed Order, to provide that the cleared swaps customer must affirm that claims to ''customer property'' as defined in SIPA or the stockbroker liquidation provisions against the BD/FCM will be subordinated to the claims of securities customers and security-based swap customers. This modification was designed to more narrowly tailor the subordination to the portion of the debtor BD/FCM's estate that comprises ''customer property'' under SIPA and the stockbroker liquidation schemes.[47] In other words, the intent was that the subordination not extend to the general estate.

This condition in the 2020 Proposed Order was designed to remove portfolio margin cleared swaps customers from the definitions of ''customer'' under Rule 15c3–3, SIPA, and the stockbroker liquidation provisions with respect to securities or cash held in CFTC cleared swaps customer accounts that otherwise would be subject to the segregation requirements of Rule 15c3–3 and the bankruptcy protections afforded by SIPA and the stockbroker liquidation provisions.[48] The objective was to avoid a situation where the portfolio margin cleared swaps customers would be entitled to a ratable share of ''customer property'' and other protections afforded by SIPA or the stockbroker liquidation provisions even though their assets were held in CFTC cleared swaps customer accounts that were not subject to the segregation requirements of Rule 15c3–3. Assets held in a CFTC cleared swaps customer account instead would be afforded the protections of the rules of the CFTC governing the treatment of customer margin held by BD/FCMS and DCOs as well as the protections of the CEA and commodity broker liquidation provisions. The modified condition in the 2020 Proposed Order was not intended to undermine these protections. The condition also was not intended to require portfolio margin cleared swaps customers to subordinate their claims, in the event that their claims as cleared swaps customers are not fully satisfied by the distribution of assets held in CFTC cleared swaps customer accounts, to assets that may be included in the debtor's general estate.

Commenters generally supported the Commission's proposed modification to the affirmation language to provide that a cleared swaps customer must affirm that claims to ''customer property'' as defined in SIPA or the stockbroker liquidation provisions against the BD/FCM will be subordinated to the claims of securities customers and security-based swap customers. One commenter, in supporting the modification, stated that there is no policy basis to disadvantage cleared swap customers as compared to other general creditors of a BD/FCM and, therefore, their claims to ''customer property'' should not be subordinated to claims of general creditors, but only to the claims of securities customers and security-based swap customers.[49] Two commenters supported the modifications but suggested that the Commission further tailor the language to ensure that it only requires the subordination of a customer's claims for assets subject to a portfolio margining arrangement and not to other claims the customer may have against the BD/FCM, such as, for example, separate claims the customer may have as a securities customer in relation to a securities account.[50]

The Commission agrees with these commenters that the subordination requirement can be further tailored to provide greater clarity that the subordination agreement is limited to money, securities or other property of the subordinating customer held in a CFTC cleared swaps customer account. If the subordinating customer has a separate securities account at the BD/FCM, the customer need not subordinate claims to cash or securities held in that account. To provide greater clarity on this point, the Commission is modifying the text of the subordination requirement in the 2021 Final Order. In particular, the requirement provides that cleared CDS swaps customer must agree that claims to ''customer property'' as defined in SIPA or the stockbroker liquidation provisions against the BD/FCM *with respect to the money, securities, or property identified in paragraph (b)(1)(i)* of the 2021 Final Order (*i.e.,* in the CFTC cleared swaps customer account) will be subordinated to the claims of securities customers and security-based swap customers.[51] Thus, the language of the subordination requirement explicitly links to money, securities or other property of the subordinating customer held in *a CFTC cleared swaps customer account.*

In connection with the proposed clarifications to the subordination requirement, several commenters requested that Commission confirm that current cleared swap customers would not need to amend their existing agreements to provide revised affirmations reflecting the new language prescribed by the 2020 Proposed Order.[52] Commenters suggested that the Commission clarify that affirmations provided pursuant to the 2012 Order were intended to, and should be read to, provide for subordination of claims solely to securities customers and security-based swap customers and not to general creditors.[53] One commenter stated the revised language should be required to be included in affirmations only on a going-forward basis for new cleared swap customers.[54] Another commenter stated that reviews and changes to existing documentation would be a costly and complex exercise since the documentation may form part of other clearing arrangements, and would be onerous to both BD/FCMs and their customers.[55] Another commenter stated that requiring re-documentation would place a significant burden on its member firms.[56] Commenters suggested that the Commission permit firms to notify customers of the clarification through disclosures or negative consents rather than re-documenting existing agreements.[57] Finally, one commenter requested that for BD/FCMs whose existing subordination arrangements are in compliance with the conditions under the 2020 Proposed Order but for reference to the 2012 Order, that the

[46] *See* 2012 Order, 77 FR 75220.

[47] *See* 2020 Proposed Order, 85 FR 70661.

[48] *See* 85 FR 70661.

[49] ICI Letter.

[50] FIA Letter; SIFMA AMG/MFA Letter. These commenters suggested that the affirmation language read: ''as well as an affirmation by the cleared swaps customer that solely with respect to the distribution of ''customer property'' as defined in SIPA or 11 U.S.C. 741 and, for the avoidance of doubt, without prejudice to its entitlement to ''customer property'' as defined in 11 U.S.C. 761, its claims against the BD/FCM for such money, securities or property will be subordinated to the claims of securities customers and security-based swap customers.''

[51] *See* 2021 Final Order, ¶ (b)(1)(ii). In the second sentence of paragraph (b)(1)(ii) of the 2021 Final Order, the word ''such'' was replaced with ''the'' and the phrase ''identified in paragraph (b)(1)(i) of this order'' was inserted immediately following the phrase ''money, securities or property''.

[52] FIA Letter; ICI Letter; SIFMA AMG/MFA Letter.

[53] ICI Letter.

[54] ICI Letter; FIA Letter.

[55] FIA Letter.

[56] SIFMA AMG/MFA Letter.

[57] FIA Letter; SIFMA AMG/MFA Letter.

Commission clarify that no further documentation or amendments would be required in respect to such arrangements.[58]

In response to the comments regarding whether a BD/FCM would be required to re-document existing agreements, based on the description provided by commenters of varying documentation processes and clearing arrangements among firms, BD/FCMs that have entered into non-conforming subordination agreements and other documentation with counterparties under the 2012 Order will need to determine if their existing documentation is sufficient to meet the conditions of the 2021 Final Order or if any amendments of, or other clarifications to, existing agreements is warranted. It is important that the subordination agreement of a customer be limited so that it does not extend to the general estate or to securities and cash held in a separate securities account. In response to comments regarding the intent of the modifications to the subordination language, the intent of the modifications in the 2021 Final Order to the subordination requirements in the 2012 Order is to better clarify that a cleared swaps customer is not subordinating claims to general creditors. This clarification will preserve protections for customers that are not intended to be impacted or diminished by the subordination requirement in the 2021 Final Order. In addition, in response to the comment relating to BD/FCMs whose existing subordination arrangements meet the conditions under the 2020 Proposed Order but for reference to the 2012 Order, no further documentation or amendments would be required with respect to these existing subordination agreements that reference the 2012 Order if the agreements are in compliance with the conditions of the 2021 Final Order.

In response to comments that re-documentation of existing arrangements will increase costs and burdens on firms, BD/FCMs must individually determine if their current documentation meets the conditions of the 2021 Final Order. Accordingly, costs and burdens will depend on whether existing documentation is sufficient to meet the conditions of the 2021 Final Order. To the extent a BD/FCM must re-document existing arrangements, the Commission believes such costs and burdens associated with re-documentation are necessary to protect investors. As discussed above, the conditions of the 2021 Final Order are designed to preserve customer protection by limiting the scope of the subordination agreement. Finally, in response to a comment, BD/FCMs that enter into subordination agreements with new cleared swaps customers must ensure that the affirmation required by the 2021 Final Order is executed if they wish to take advantage of the conditional exemption provided by the 2021 Final Order.

As stated above, BD/FCMs that have entered into non-conforming subordination agreements and other documentation with counterparties under the 2012 Order will need to determine if their existing documentation is sufficient to meet the conditions of the 2021 Final Order or if any amendments of, or other clarifications to, existing agreements is warranted. The Commission recognizes that these determinations and any subsequent amendments or other clarifications to existing arrangements may take additional time to implement. Consequently, the Commission is, by order, extending the time for a BD/FCM to meet the conditions in paragraph (b)(1)(ii) of the 2021 Final Order until February 1, 2022, at which time BD/FCMs must satisfy all applicable conditions of the 2021 Final Order to continue to avail themselves of the conditional exemption.

The second BD/FCM condition in the Final 2020 Order applies with respect to transactions involving *affiliates* of the BD/FCM and consists of three requirements. The Commission did not receive any comments on the first requirement and is adopting it as proposed.[59] Under the this requirement, the BD/FCM must maintain money, securities, and property of affiliates received to margin, guarantee, or secure positions consisting of cleared CDS in a ''cleared swaps proprietary account'' as defined in CFTC Rule 22.1 for the purpose of clearing such positions under the CDS portfolio margin program.[60] The purpose of this requirement is that under the CFTC regulatory framework certain affiliates are not treated as cleared swaps customers and their assets are held in proprietary accounts as distinct from CFTC cleared swaps customer accounts.[61]

The comments discussed above with respect to the scope of the subordination agreement apply to the second requirement, which the Commission is modifying consistent with changes to the customer subordination requirement discussed above. Under this requirement, the BD/FCM must enter into a non-conforming subordination agreement with an affiliate.[62] The non-conforming subordination agreement must contain: (1) A specific acknowledgment by the affiliate that the money, securities or property *identified in paragraph (b)(2)(i)* of the 2021 Final Order (*i.e.,* in the cleared swaps proprietary account) will not receive customer treatment under the Exchange Act or SIPA or be treated as customer property in a stockbroker liquidation of the BD/FCM, and that such money, securities or property will be held in a proprietary account in accordance with the CFTC requirements and will be subject to any applicable protections under the commodity broker liquidation provisions; and (2) an affirmation by the affiliate that claims to ''customer property'' as defined in SIPA or 11 U.S.C. 741 against the BD/FCM *with respect to the money, securities, or property identified in paragraph (b)(2)(i)* of the 2021 Final Order will be subordinated to the claims of securities customers and security-based swap customers.

As discussed above, these modifications provide greater clarity that the scope of the subordination only extends to money, securities, or other property held in the subordinating person's CFTC cleared customer or proprietary account. The modifications also provide greater clarity that the person need not subordinate claims to money, securities, or other property held in the subordinating person's CFTC cleared customer or proprietary account to the claims of general creditors.

This requirement is designed to help ensure that affiliates clearly understand that any customer protection treatment otherwise available with respect to securities transactions under the Exchange Act, SIPA, or the stockbroker liquidation provisions will not be available and the account would be treated as a proprietary account (and not a CFTC cleared swaps customer account) under the CEA. Consistent with the condition above with respect to cleared swaps customers that are not affiliates, this condition is intended to remove affiliates from the definitions of ''customer'' under Rule 15c3–3, SIPA,

[58] SIFMA AMG/MFA Letter.

[59] *See* 2021 Final Order, ¶ (b)(2); *see also* 2020 Proposed Order, 85 FR 70661.

[60] *See* 2021 Final Order, ¶ (b)(2)(i).

[61] *See* 17 CFR 22.1. The Commission believes that this condition is appropriate because affiliates of a BD/FCM that are not otherwise excluded from the definition of ''customer'' in Exchange Act Rules 8c–1 and 15c2–1 are customers whose securities positions cannot be commingled with the broker-dealer's own proprietary securities positions and therefore could not be held in a cleared swaps account.

[62] *See* 2021 Final Order, ¶ (b)(2)(ii).

and the stockbroker liquidation provisions with respect to securities or cash held in cleared swaps proprietary accounts that otherwise would be subject to the segregation requirements of Rule 15c3–3 and the bankruptcy protections afforded by SIPA and the stockbroker liquidation provisions.

The Commission did not receive any comments with respect to the third requirement of the second condition and is adopting it with a conforming modification.[63] As proposed, this condition required that the BD/FCM obtain from the affiliate an opinion of counsel that the affiliate is legally authorized *to subordinate all of its claims against the BD/FCM to those of securities customers and security-based swap customers.*[64] Consistent with the changes discussed above with respect to the scope of the subordination, the Commission modified this condition so that it requires the BD/FCM obtain from the affiliate an opinion of counsel that the affiliate is legally authorized to *enter into the subordination agreement required by paragraph (b)(2)(ii) of the order.* This conforms the condition to the modifications discussed above with respect to the scope of the subordination. This condition is designed to help ensure that affiliates of the BD/FCM do not place any assets in the proprietary account that the affiliate is not legally authorized to subordinate. Finally, consistent with the changes discussed above with respect to the scope of the subordination, the Commission is, by order, extending the time for a BD/FCM to meet the conditions in paragraph (b)(2)(ii) of the 2021 Final Order until February 1, 2022, at which time BD/FCMs must satisfy all applicable conditions of the 2021 Final Order to continue to avail themselves of the conditional exemption.

The condition in paragraph (b)(3) of the 2012 Order provides that the BD/FCM must require minimum margin levels with respect to any customer transaction in the CDS portfolio margin program at least equal to the amount determined using a margin methodology established and maintained by the BD/FCM that has been approved by the Commission or the Commission staff.[65] A commenter responding to the issuance of the 2012 Order supported the requirement for a BD/FCM to assess the credit risk of counterparties based on the BD/FCM's own risk management standards, but argued that requiring a unique margin model beyond the BD/FCM's own credit risk assessment is unwarranted.[66] This commenter also stated that this condition ''deters'' efficiency, capital formation, and competition.[67] Another commenter responding to the issuance of the 2012 Order argued that the condition undermines a fundamental benefit of central clearing: The ability of market participants to rely on clearing agency/DCO margin requirements.[68] This commenter believes that this condition reduces transparency and the ability to anticipate and verify margin calls, and that it discourages entities from entering the cleared CDS market.[69]

In the context of the SEC's capital, margin and segregation rulemaking for SBSDs, another commenter expressed concern that the conditions in the 2012 Order have proven too restrictive to support a robust market for cleared CDS.[70] More specifically, this commenter recommended that both the CFTC and SEC recognize a harmonized portfolio margin approach for cleared CDS that defers to the clearing agency/DCO margin methodologies.[71] Finally, a commenter expressed concern that the margin requirements imposed by the Commission have delayed voluntary buy-side clearing of single-name CDS, with resulting adverse effects on trading volume and liquidity.[72]

The vast majority of the BD/FCM clearing members of ICE Clear Credit have obtained approval of their margin methodologies from Commission staff.[73] Furthermore, each BD/FCM that has received approval of its margin methodology already had existing margin models in place prior to applying to the Commission. Therefore, the firms needed to make some adjustments to their models in order to meet the minimum qualitative and quantitative standards set forth in the BD/FCM staff letters, but did not need to develop new margin models. To date, all BD/FCMs that have submitted applications to Commission staff to approve their internal margin methodologies have received approval.

In response to these comments, the Commission believes that it can promote the prudent operation of the BD/FCMs through a process of approving their internal risk management programs (rather than their internal margin methodologies), as discussed below. This may increase transparency for market participants in terms of being able to anticipate margin requirements generated by their cleared CDS portfolios, as the clearing agency/DCO margin methodology will generate the regulatory margin requirement across all the BD/FCMs. Accordingly, the Commission proposed modifying the condition in paragraph (b)(3) of the 2012 Order to eliminate the requirement that the Commission or Commission staff approve the BD/FCM's margin methodology.[74] Instead, the Proposed

[63] *See* 2021 Final Order, ¶ (b)(2)(iii); *see also* 2020 Proposed Order, 85 FR 70661–62.

[64] *See* 2020 Proposed Order, 85 FR 70661–62. The 2012 Order required that the BD/FCM obtain from the affiliate an opinion of counsel that the affiliate is legally authorized to subordinate all of its claims against the BD/FCM to those of customers. *See* 2012 Order, 77 FR 75220.

[65] *See* 2012 Order, 77 FR 75220.

[66] *See* Letter from Stuart J. Kaswell, Executive Vice President & Managing Director, General Counsel, Managed Funds Association; Carl B. Wilkerson, Vice President & Chief Counsel, Securities & Litigation, American Council of Life Insurers; and Jiří Krol, Director of Government and Regulatory Affairs, Alternative Investment Management Association (Dec. 27, 2013) (''MFA/ACLI/AIMA 12/27/2013 Letter'') (comment to the 2012 Order), *available at https://www.sec.gov/comments/s7-13-12/s71312.shtml; see also* Letter from Stuart J. Kaswell, Executive Vice President & Managing Director, General Counsel, Managed Funds Association; Carl B. Wilkerson, Vice President & Chief Counsel, Securities & Litigation, American Council of Life Insurers; and Jiří Krol, Director of Government and Regulatory Affairs, Alternative Investment Management Association (May 10, 2013) (comment to the 2012 Order), *available at https://www.sec.gov/comments/s7-13-12/s71312.shtml. See also* 2020 Proposed Order, 85 FR 70662.

[67] MFA/ACLI/AIMA 12/27/2013 Letter. *See also* 2020 Proposed Order, 85 FR 70662.

[68] *See* Letter from Adam C. Cooper, Senior Managing Director and Chief Legal Officer, Citadel LLC (Feb. 2, 2016) (''Citadel 2/2/16 Letter'') (comment to the 2012 Order), *available at https://www.sec.gov/comments/s7-13-12/s71312.shtml. See also* 2020 Proposed Order, 85 FR 70662.

[69] Citadel 2/2/16 Letter; Letter from Laura Harper Powell, Associate General Counsel, Managed Funds Association, and Adam Jacobs-Dean, Managing Director, Global Head of Markets Regulation, Alternative Investment Management Association (Nov. 19, 2018) (comment to the Commission's capital, margin, and segregation rulemaking for SBSDs), *available at https://www.sec.gov/comments/s7-08-12/s70812.shtml. See also* 2020 Proposed Order, 85 FR 70662.

[70] *See* Letter from Walt L. Lukken, President and Chief Executive Office, Futures Industry Association (Nov. 29, 2018) (''FIA 11/29/18 Letter'') (comment to the Commission's capital, margin, and segregation rulemaking for SBSDs), *available at https://www.sec.gov/comments/s7-08-12/s70812.shtml. See also* 2020 Proposed Order, 85 FR 70662.

[71] Letter from Walt L. Lukken, President and Chief Executive Office, Futures Industry Association (Nov. 19, 2018) (comment to the Commission's capital, margin, and segregation rulemaking for SBSDs), *available at https://www.sec.gov/comments/s7-08-12/s70812.shtml;* FIA 11/29/18 Letter. *See also* 2020 Proposed Order, 85 FR 70662.

[72] *See* Letter from Stuart J. Kaswell, Executive Vice President & Managing Director, General Counsel, Managed Funds Association (May 18, 2017) (comment to the Commission's capital, margin, and segregation rulemaking for SBSDs), *available at https://www.sec.gov/comments/s7-08-12/s70812.shtml. See also* 2020 Proposed Order, 85 FR 70662.

[73] *See* ICC membership, *available at https://www.theice.com/clear-credit/participants.* Based on Division staff experience in monitoring the CDS portfolio margin program, the vast majority of positions are being cleared through ICE Clear Credit, and to a lesser extent, ICE Clear Europe.

[74] *See* 2020 Proposed Order, 85 FR 70662.

2020 Order would have required the BD/FCM to adopt an internal risk management program that is reasonably designed to identify, measure, and manage the risks arising from its participation in the CDS portfolio margin program that has been approved in advance by the Commission or the Commission staff and that meets the standards described below (''internal risk management program'').

An internal risk management program would facilitate the identification, measurement, and management of a broader range of risks than those covered by the clearing agency/DCO margin methodology and, consequently, help ensure that the BD/FCMs operate in a prudent manner with respect to the CDS portfolio margin program. Further, an internal risk management program entails a more comprehensive set of measures to mitigate risk than a margin methodology.[75] Consequently, based on the Commission staff's experience gained in monitoring the CDS portfolio margin program, approving a firm's internal risk management program (rather than its internal margin methodology) may foster a more robust approach to managing risk by BD/FCMs. This approach to managing risk also would promote consistency with the Commission's final capital rules for SBSDs, which include risk management requirements, as well as with the regulatory approach adopted by the CFTC with respect to the portfolio margining of cleared CDS.[76] The requirement to have an internal risk management program also is a condition in the BD/FCM staff letters and all the firms operating under the 2012 Order have implemented such programs.

The requirement that a BD/FCM independently measure risk by developing and using its own internal model is not designed to impose a margin collection requirement (or capital charge) or diminish the role of the clearing agency/DCO margin methodology. Rather, it is intended to require the BD/FCM to independently measure the potential future credit risk to cleared swaps customers and affiliates participating in the CDS portfolio margin program under a different stress scenario in order to better understand risks and address them as the firm deems appropriate (*e.g.,* through risk limits, threshold triggers, house margin, heightened monitoring, or other controls).

Commenters generally supported the Commission's proposed standards for an internal risk management program.[77] Two commenters requested that the Commission permit BD/FCMs to rely on the clearing agency/DCO's margin methodology, which is subject to supervision by the CFTC and Commission, unless one of its supervisors has a reasonable basis for concluding that the methodology underestimates the risk or is otherwise inconsistent with the internal risk management program.[78] This alternative, however, would not cover the broader range of risks included in an internal risk management program. Prudent firms establish and maintain integrated internal risk management programs that include policies and procedures designed to help ensure an awareness of, and accountability for, the risks taken throughout the firm and to develop tools to address those risks. For example, there may be idiosyncratic risk factors with respect to a cleared swaps customer, an affiliate, or the BD/FCM's financial condition that are not covered by the margin methodology of the clearing agency/DCO.[79] For these reasons, relying solely on a clearing agency/DCO's margin methodology, as requested by commenters, would not be an adequate alternative to implementing a broader risk management program in terms of managing the risk of cleared CDS in a portfolio margin account.

For the foregoing reasons, the Commission is adopting the risk management condition as proposed in the 2020 Proposed Order.[80] In doing so, the Commission is eliminating the condition in the 2012 Order that the BD/FCM must require minimum margin levels with respect to any customer transaction in the CDS portfolio margin program at least equal to the amount determined using a margin methodology established and maintained by the BD/FCM that has been approved by the Commission or the Commission staff.[81] A BD/FCM seeking approval of its internal risk management program will need to submit sufficient information for the Commission or Commission staff to be able to make a determination whether its program meets the required standards described below.[82] In reviewing this information, the Commission or the Commission staff will be guided by these standards.[83] If a BD/FCM's internal risk management program is approved for purposes of the 2021 Final Order, the program will be subject to ongoing supervision and monitoring by the Commission.[84]

The Commission proposed three sets of standards for the internal risk management program in the 2020 Proposed Order.[85] The Commission did not receive any comments on the standards and is adopting them as proposed in the 2020 Proposed Order.

The first standard is that the BD/FCM must calculate a future credit exposure for each cleared swaps customer and affiliate (sometimes each a ''counterparty'') using a proprietary methodology that meets specified minimum quantitative and qualitative model standards (''internal risk model'').[86] The quantitative standards are that the internal risk model:

- Estimates a potential future exposure over a minimum 10-day horizon and 99% confidence level and captures all material risk factors, including but not limited to general movements in credit spread term structure, basis risk between index and single name positions, and interest rate risk;

[75] *See, e.g.,* 17 CFR 240.15c3–1e(d)(1) (''The VaR model used to calculate market and credit risk for a position must be integrated into the daily internal risk management system of the broker or dealer[.]'').

[76] *See* Capital, Margin, and Segregation Adopting Release, 84 FR 43905 (''The Commission proposed that nonbank SBSDs be required to comply with Rule 15c3–4 to promote the establishment of effective risk management control systems by these firms.''); and 2013 CFTC Portfolio Margin Order (requiring participants to ''take appropriate measures to identify, measure, and monitor financial risk associated with carrying the Security-Based CDS in a cleared swaps account and implement risk management procedures to address those financial risks'').

[77] FIA Letter; SIFMA AMG/MFA Letter.

[78] FIA Letter; SIFMA AMG/MFA Letter.

[79] *See* 2020 Proposed Order, 85 FR 70662.

[80] *See* 2021 Final Order, ¶ (b)(3). The 2021 Final Order contains a provision finding that the BD/FCMs that have received previous approval of their internal margin methodology from the Division staff are deemed to have approved internal risk management programs for purposes of paragraph (b)(3) of the order. These BD/FCMs will no longer be required to have minimum margin levels with respect to any customer transaction in a CDS portfolio margin program at least equal to the amount determined using a margin methodology approved by the Commission or the Commission staff, as required by the 2012 Order. They must instead comply with the internal risk management program standards under condition (b)(3) of the 2021 Final Order. One commenter supported this approach. FIA Letter.

[81] Nothing in the 2021 Final Order precludes a BD/FCM from setting higher ''house'' margin requirements for some or all of its customers. *See* 17 CFR 39.13(g)(8).

[82] *See generally* 17 CFR 240.15c3–1e(a)(1). A BD/FCM must submit information only to the extent it is relevant to the portfolio margining of cleared CDS. The BD/FCM may seek confidential treatment for information submitted as part of such application. The Commission may approve a BD/FCM's internal risk management program that meets the standards of paragraph (c) of the 2021 Final Order through an order. The Commission staff may also approve a BD/FCM's internal risk management program that meets the standards of paragraph (c) of the 2021 Final Order through the same process used to issue the BD/FCM staff letters pursuant to the 2012 Order.

[83] *See supra* note 81.

[84] *See* 2021 Final Order, ¶ (c)(1)(ii)(D).

[85] *See* 2020 Proposed Order, 85 FR 70663–64.

[86] *See* 2021 Final Order, ¶ (c)(1).

• Includes a concentration/liquidity requirement; and

• Includes a jump-to-default requirement for the sale of CDS protection equal to the largest loss of a single name exposure assuming a conservative recovery rate that may not exceed 40%.

The qualitative standards are that:

• The internal risk model must be adequately documented and the model documentation must provide a description of the model assumptions, data inputs, parameters, and methodologies employed to measure risk;

• The internal risk model must be subject to an annual model review by a model group that is independent of the business function;

• The internal risk model must be subject to at least quarterly backtesting by counterparty or account; and

• The BD/FCM must provide written notice to the Commission or Commission staff prior to implementing any material change to its internal risk model.

These quantitative and qualitative requirements generally are consistent with the quantitative and qualitative requirements for internal risk models under Appendix E to Rule 15c3–1 and under new Rule 18a–1. These rules permit certain broker-dealers and SBSDs, respectively, to compute capital charges using internal models.[87] For example, the standards in the proposed order generally would require that the model cover a 10-day horizon, 99% confidence level, and material risks, and that the BD/FCM backtest the model and subject it to review.[88]

The second standard for the internal risk management program is that it must have the following minimum risk management elements:

• The BD/FCM must have standards to measure and manage risk exposure arising from counterparties' CDS portfolios that are independent of any central counterparty margin methodology;

• The BD/FCM must have an internal credit risk rating model that assesses the credit risk of each individual counterparty;

• The BD/FCM's monitoring of credit risk must include the prudent setting of an exposure limit for each individual counterparty, and the exposure limit must be reviewed if the counterparty's credit risk profile changes and at least quarterly;

• The BD/FCM must have the ability to limit or reduce the exposure to a counterparty through the collection of additional margin;

• The BD/FCM must have documented procedures to value positions conservatively in view of current market prices and the amount that might be realized upon liquidation; and

• The BD/FCM must have well-defined procedures and systems in place for the daily collection and payment of initial and variation margin.[89]

The standards requirement is a condition in the BD/FCM staff letters. These risk management standards are designed to require a BD/FCM to take prudent steps to protect the firm from losses that can result from failing to account for and control risk with respect to its CDS portfolio margin program. Requiring a BD/FCM to incorporate these proposed standards is designed to promote the establishment of effective internal risk management programs to address the risks of portfolio margining cleared CDS.

The third standard for the internal risk management program is that the BD/FCM must report to the Commission and FINRA staffs on a monthly basis within 5 business days after month end or as otherwise requested details of its top 25 counterparties' portfolios as measured by net credit exposure as well as the top 25 counterparties' portfolios as measured by gross notional amount.[90] This requirement is a condition in the BD/FCM staff letters. Based on Commission staff's experience with the BD/FCM staff letter requirements, this monthly reporting requirement is appropriate as it will assist Commission staff in monitoring the risk to the BD/FCM arising from its portfolio margining of cleared CDS. Understanding the magnitude of this risk will assist the Commission staff in evaluating the appropriateness of a given firm's internal risk management program in terms of its procedures and controls to mitigate risk.

The 2021 Final Order does not include other conditions in the BD/FCM staff letters, including the capital concentration charge. Based on Commission staff experience monitoring the BD/FCMs participating in the CDS portfolio margin program, the Commission believes that the capital concentration charge and other conditions in the BD/FCM staff letters are not necessary in light of the requirement to have a reasonably designed internal risk management program. A reasonably designed internal risk management program will provide a BD/FCM the tools to better understand the risks that arise from its portfolio margining of cleared CDS and address them as the firm deems appropriate (*e.g.,* through risk limits, threshold triggers, house margin, heightened monitoring, or other controls). Therefore, the Commission is not incorporating these conditions into the 2021 Final Order.

The Commission did not receive any comments on the fourth BD/FCM condition in the 2020 Proposed Order and is adopting it as proposed.[91] This condition requires that the BD/FCM be in compliance with applicable laws and regulations relating to risk management, capital, and liquidity, and be in compliance with applicable clearing agency/DCO rules and CFTC requirements (including margin, segregation, and related books and records provisions) with respect to CFTC cleared swaps customer accounts and cleared swaps proprietary accounts subject to the CDS portfolio margin program.[92] The purpose of this condition is to help ensure that the exemption is available only when the BD/FCM is in compliance with applicable regulatory requirements. The Commission received no comments on this condition and is adopting it as proposed in the 2020 Proposed Order.[93]

The Commission did not receive any comments on the fifth BD/FCM condition in the 2020 Proposed Order and is adopting it as proposed.[94] This condition requires that each cleared swaps customer and affiliate of the BD/FCM participating in the CDS portfolio margin program be an ''eligible contract participant.'' [95] As with the third condition in the 2021 Final Order for clearing agency/DCOs, it would be appropriate to limit this exemption to cleared CDS entered into with eligible contract participants. Eligible contract participants should have the expertise or resources to effectively determine the risks associated with engaging in these types of transactions.

The Commission did not receive any comments on the sixth BD/FCM condition in the 2020 Proposed Order and is adopting it as proposed.[96] This condition requires that, before receiving

[87] *See* 17 CFR 240.15c3–1e and 18a–1.

[88] *See* 17 CFR 15c3–1e(d).

[89] *See* 2021 Final Order, ¶ (c)(2).

[90] *See* 2021 Final Order, ¶ (c)(3).

[91] *See* 2020 Proposed Order, 85 FR 70664.

[92] *See* 2021 Final Order, ¶ (b)(4).

[93] *See* 2020 Proposed Order, 85 FR 70664.

[94] *See* 2020 Proposed Order, 85 FR 70664.

[95] *See* 2021 Final Order, ¶ (b)(5). The 2012 Order required that each customer of the BD/FCM participating in a program to commingle and portfolio margin CDS be an ''eligible contract participant'' as defined in Section 1a(18) of the CEA. 77 FR 75220.

[96] *See* 2020 Proposed Order, 85 FR 70664.

any money, securities, or property of a cleared swaps customer or affiliate to margin, guarantee, or secure positions consisting of cleared CDS, the BD/FCM must furnish to the cleared swaps customer or affiliate a disclosure document containing: (1) A statement indicating that the cleared swaps customer's or affiliate's money, securities, and property will be held in a CFTC cleared swaps account, and that the cleared swaps customer or affiliate has elected to seek protections under the commodity broker liquidation provisions with respect to such money, securities, and property; and (2) a statement that the broker-dealer segregation requirements of Sections 15(c)(3) and 3E of the Exchange Act and the rules thereunder, and any customer protections under SIPA and the stockbroker liquidation provisions, will not apply to such cleared swaps customer or affiliate money, securities, and property.[97] The disclosure document must be provided to the cleared swaps customer or affiliate at or prior to the time that the cleared swaps customer or affiliate opens the CFTC cleared swaps account and, in all cases, prior to the BD/FCM receiving any money, securities or property into the CFTC cleared swaps account of the cleared swaps customer or affiliate. This condition is designed to provide market participants that elect to participate in the CDS portfolio margin program with important disclosures regarding the legal framework that will govern their transactions.

For the reasons discussed above, the Commission finds it appropriate in the public interest and consistent with the protection of investors to exempt clearing agency/DCOs and BD/FCMs from compliance with certain provisions of the Exchange Act in connection with a program to portfolio margin cleared swaps customer and affiliate positions in cleared CDS that are swaps and security-based swaps in a segregated account established and maintained in accordance with Section 4d(f) of the CEA (in the case of a cleared swaps customer) or a cleared swaps proprietary account (in the case of an affiliate).

[97] *See* 2021 Final Order, ¶ (b)(6).

IV. Conclusion

Pursuant to Sections 3E(c)(2)[98] and 36[99] of the Exchange Act:

It is hereby ordered that any broker-dealer also registered as a futures commission merchant that has received approval of its margin methodology by the Commission or Commission staff prior to the date of this order is deemed to have an internal risk management program that has been approved by the Commission or the Commission staff as required by paragraph (b)(3) of this order. *It is hereby further ordered* that the following exemptions from Exchange Act requirements will apply:

(a) *Exemption for dually-registered clearing agencies/derivatives clearing organizations.*

A clearing agency registered pursuant to Section 17A of the Exchange Act and registered as a derivatives clearing organization pursuant to Section 5b of the CEA (a ''clearing agency/DCO'') will be exempt from Sections 3E(b), (d), and (e) of the Exchange Act and any rules thereunder, solely to perform the functions of a clearing agency for credit default swaps (''CDS'') under a program to commingle and portfolio margin cleared CDS for cleared swaps customer and affiliate positions, subject to the following conditions:

(1) The clearing agency/DCO has obtained any other relief needed to permit its clearing members that are registered under Section 15(b) of the Exchange Act (other than paragraph (11) thereof) and also registered as a futures commission merchant pursuant to Section 4f(a)(1) of the CEA (a ''BD/FCM'') (at the BD/FCM's election), to maintain cleared swaps customer or affiliate money, securities, and property received by the BD/FCM to margin, guarantee, or secure cleared swaps customer or affiliate positions in cleared CDS, which include both swaps and security-based swaps, in a segregated account established and maintained in accordance with Section 4d(f) of the CEA and rules thereunder (in the case of a cleared swaps customer) or a cleared swaps proprietary account (in the case of an affiliate) for the purpose of clearing (as a clearing member of the clearing agency/DCO) such cleared swaps customer or affiliate positions under a program to commingle and portfolio margin CDS.

(2) The clearing agency/DCO has appropriate rules and operational practices to permit a BD/FCM that is a clearing member (at the BD/FCM's election) to maintain cleared swaps customer or affiliate money, securities, and property received by the BD/FCM to margin, guarantee, or secure cleared swaps customer or affiliate positions in cleared CDS, which include both swaps and security-based swaps, in a segregated account established and maintained in accordance with Section 4d(f) of the CEA and rules thereunder (in the case of a cleared swaps customer) or a cleared swaps proprietary account (in the case of an affiliate) for the purpose of clearing (as a clearing member of the clearing agency/DCO) such cleared swaps customer or affiliate positions under a program to commingle and portfolio margin CDS.

(3) The rules of the clearing agency/DCO require that each cleared swaps customer and affiliate of the BD/FCM participating in a program to commingle and portfolio margin CDS must be an ''eligible contract participant'' as defined in Section 1a(18) of the CEA.

(b) *Exemption for certain BD/FCMs that elect to offer a program to commingle and portfolio margin cleared swaps customer and affiliate positions in cleared CDS.* Solely to perform the functions of a BD/FCM for cleared CDS, with respect to any cleared swaps customer or affiliate money, securities, and property received by the BD/FCM to margin, guarantee, or secure cleared swaps customer or affiliate positions in security-based swaps included in a segregated account established and maintained in accordance with Section 4d(f) of the CEA and rules thereunder (in the case of a cleared swaps customer) or a cleared swaps proprietary account (in the case of an affiliate) under a program to commingle and portfolio margin cleared swaps customer or affiliate positions in CDS, a BD/FCM will be exempt from Exchange Act Sections 3E(b), (d), and (e), and Section 15(c)(3) and Rule 15c3–3 thereunder and any requirement to treat an affiliate (as defined in association with the definition of ''cleared swaps proprietary account'' pursuant to CFTC

[98] 15 U.S.C. 78c–5(c)(2). Section 3E(c)(2) of the Exchange Act provides that the Commission may, notwithstanding Section 3E(b) of the Exchange Act, by rule, regulation, or order prescribe terms and conditions under which any money, securities, or property of a customer with respect to cleared security-based swaps may be commingled and deposited with any other money, securities, or property received by the broker-dealer or SBSD and required by the Commission to be separately accounted for and treated and dealt with as belonging to the security-based swap customer of the broker-dealer or SBSD.

[99] 15 U.S.C. 78mm. Section 36 of the Exchange Act authorizes the Commission to conditionally or unconditionally exempt, by rule, regulation, or order any person, security, or transaction (or any class or classes of persons, securities, or transactions) from any provision of the Exchange Act or any rule or regulation thereunder, to the extent such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.

Rule 22.1) as a customer for purposes of Section 8 of the Exchange Act and Exchange Act Rules 8c–1 and 15c2–1 thereunder, subject to the following conditions:

(1) With respect to cleared swaps customers that are not affiliates of the BD/FCM,

(i) The BD/FCM must maintain cleared swaps customer money, securities, and property received to margin, guarantee or secure cleared swaps customer positions consisting of cleared CDS, which include both swaps and security-based swaps, in a segregated account established and maintained in accordance with Section 4d(f) of the CEA and rules thereunder for the purpose of clearing (as a clearing member or through a clearing member of a clearing agency/DCO operating pursuant to the exemption in paragraph (a) above) such cleared swaps customer positions under a program to commingle and portfolio margin CDS; and

(ii) The BD/FCM must enter into a non-conforming subordination agreement with each cleared swaps customer by no later than February 1, 2022. The agreement must contain a specific acknowledgment by the cleared swaps customer that the money, securities or property identified in paragraph (b)(1)(i) of this order will not receive customer treatment under the Exchange Act or SIPA or be treated as ''customer property'' as defined in 11 U.S.C. 741 in a liquidation of the BD/FCM and that such money, securities or property will be subject to any applicable protections under Subchapter IV of Chapter 7 of Title 11 of the United States Code and rules and regulations thereunder; as well as an affirmation by the cleared swaps customer that claims to ''customer property'' as defined in SIPA or 11 U.S.C. 741 against the BD/FCM with respect to the money, securities, or property identified in paragraph (b)(1)(i) of this order will be subordinated to the claims of securities customers and security-based swap customers.

(2) With respect to affiliates of the BD/FCM,

(i) The BD/FCM maintains money, securities, and property of affiliates received to margin, guarantee, or secure positions consisting of cleared CDS, which include both swaps and security-based swaps, in a cleared swaps proprietary account for the purpose of clearing (as a clearing member of a clearing agency/DCO operating pursuant to the exemption in paragraph (a) above) such positions under a program to commingle and portfolio margin CDS;

(ii) The BD/FCM enters into a non-conforming subordination agreement with each affiliate by no later than February 1, 2022. The agreement must contain a specific acknowledgment by the affiliate that the money, securities or property identified in paragraph (b)(2)(i) of this order will not receive customer treatment under the Exchange Act or SIPA or be treated as ''customer property'' as defined in 11 U.S.C. 741 in a liquidation of the BD/FCM, and that such money, securities or property will be held in a proprietary account in accordance with the CFTC requirements and will be subject to any applicable protections under Subchapter IV of Chapter 7 of Title 11 of the United States Code and rules and regulations thereunder; as well as an affirmation by the affiliate that claims to ''customer property'' as defined in SIPA or 11 U.S.C. 741 against the BD/FCM with respect the money, securities, or property identified in paragraph (b)(2)(i) of this order will be subordinated to the claims of securities customers and security-based swap customers; and

(iii) The BD/FCM obtains from the affiliate an opinion of counsel that the affiliate is legally authorized to enter into the subordination agreement required by paragraph (b)(2)(ii) of this order.

(3) The BD/FCM has adopted an internal risk management program that is reasonably designed to identify, measure, and manage the risks arising from its program to allow cleared swaps customers and affiliates to commingle and portfolio margin CDS that has been approved in advance by the Commission or the Commission staff and meets the standards in paragraph (c) of this order.

(4) The BD/FCM must be in compliance with applicable laws and regulations relating to risk management, capital, and liquidity, and must be in compliance with applicable clearing agency/DCO rules and CFTC requirements (including segregation and related books and records provisions) for accounts established and maintained in accordance with Section 4d(f) of the CEA and rules thereunder (in the case of cleared swaps customers) and for cleared swaps proprietary accounts (in the case of affiliates), and subject to a program to commingle and portfolio margin CDS.

(5) Each cleared swaps customer and affiliate of the BD/FCM participating in a program to commingle and portfolio margin CDS is an ''eligible contract participant'' as defined in Section 1a(18) of the CEA.

(6) Before receiving any money, securities, or property of a cleared swaps customer or affiliate to margin, guarantee, or secure positions consisting of cleared CDS, which include both swaps and security-based swaps, under a program to commingle and portfolio margin CDS, the BD/FCM must furnish to the cleared swaps customer or affiliate a disclosure document containing the following information:

(i) A statement indicating that the cleared swaps customer's or affiliate's money, securities, and property will be held in an account maintained in accordance with the segregation requirements of Section 4d(f) of the CEA (in the case of a cleared swaps customer) or a cleared swaps proprietary account (in the case of an affiliate), and that the cleared swaps customer or affiliate has elected to seek protections under Subchapter IV of Chapter 7 of Title 11 of the United States Code and the rules and regulations thereunder with respect to such money, securities, and property; and

(ii) A statement that the broker-dealer segregation requirements of Section 15(c)(3) and Section 3E of the Exchange Act and the rules thereunder, and any customer protections under SIPA and the stockbroker liquidation provisions, will not apply to such cleared swaps customer or affiliate money, securities, and property.

(c) *Standards for internal risk management program.* The internal risk management program required pursuant to paragraph (b)(3) of this order must have the following standards in place:

(1) *Internal Risk Model.* The BD/FCM must calculate a future credit exposure for each cleared swaps customer and affiliate (each a ''counterparty'') using its own proprietary methodology (''internal risk model'') subject to the following minimum quantitative and qualitative model standards:

(i) *Quantitative Requirements.* (A) The internal risk model must estimate a potential future exposure over a minimum 10-day horizon and 99% confidence level and capture all material risk factors, including but not limited to general movements in credit spread term structure, basis risk between index and single name positions, and interest rate risk;

(B) The internal risk model must include a concentration/liquidity requirement; and

(C) The internal risk model must include a jump-to-default requirement for the sale of CDS protection equal to the largest loss of a single name exposure assuming a conservative recovery rate that may not exceed 40%.

(ii) *Qualitative Requirements.* (A) The internal risk model must be adequately documented and the documentation must provide a description of the model

assumptions, data inputs, parameters, and methodologies employed to measure risk;

(B) The internal risk model must be subject to an annual model review by a model group that is independent of the business function;

(C) The internal risk model must be subject to at least quarterly backtesting by counterparty or account; and

(D) The BD/FCM must provide written notice to the Commission or Commission staff prior to implementing any material change to its internal risk model.

(2) *Minimum Risk Management System Standards.* (A) The BD/FCM must maintain risk management system standards to measure and manage risk exposure arising from counterparties' CDS portfolios that are independent of any central counterparty margin methodology;

(B) The BD/FCM must have an internal credit risk rating model that assesses the credit risk of each individual counterparty;

(C) The BD/FCM's monitoring of credit risk must include the prudent setting of an exposure limit for each individual counterparty and the exposure limit must be reviewed if the counterparty's credit risk profile changes and at least quarterly;

(D) The BD/FCM must have the ability to limit or reduce the exposure to a counterparty through the collection of additional margin;

(E) The BD/FCM must have documented procedures to value positions conservatively in view of current market prices and the amount that might be realized upon liquidation; and

(F) The BD/FCM must have well-defined procedures and systems in place for the daily collection and payment of initial and variation margin.

(3) *Monthly Reporting.* The BD/FCM must report to the Commission and FINRA staffs on a monthly basis within 5 business days after month end or as otherwise requested details of its top 25 counterparties' portfolios as measured by net credit exposure as well as the top 25 counterparties' portfolios as measured by gross notional amount.

By the Commission.

J. Matthew DeLesDernier,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–480, OMB Control No. 3235–0537]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Regulation S–P

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in the privacy notice and opt out notice provisions of Regulation S–P—Privacy of Consumer Financial Information (17 CFR part 248, subpart A) under the Securities Exchange Act of 1934 (''Exchange Act'') (15 U.S.C. 78a *et seq.*).

The privacy notice and opt out notice provisions of Regulation S–P (the ''Rule'') implement the privacy notice and opt out notice requirements of Title V of the Gramm-Leach-Bliley Act (''GLBA''), which include the requirement that, at the time of establishing a customer relationship with a consumer and not less than annually during the continuation of such relationship, a financial institution shall provide a clear and conspicuous disclosure to such consumer of such financial institution's policies and practices with respect to disclosing nonpublic personal information to affiliates and nonaffiliated third parties (''privacy notice''). Title V of the GLBA also provides that, unless an exception applies, a financial institution may not disclose nonpublic personal information of a consumer to a nonaffiliated third party unless the financial institution clearly and conspicuously discloses to the consumer that such information may be disclosed to such third party; the consumer is given the opportunity, before the time that such information is initially disclosed, to direct that such information not be disclosed to such third party; and the consumer is given an explanation of how the consumer can exercise that nondisclosure option (''opt out notice''). The Rule applies to broker-dealers, investment advisers registered with the Commission, and investment companies (''covered entities'').

Commission staff estimates that, as of June 30, 2021, the Rule's information collection burden applies to approximately 21,875 covered entities (approximately 3,560 broker-dealers, 14,381 investment advisers registered with the Commission, and 3,934 investment companies). In view of (a) the minimal recordkeeping burden imposed by the Rule (since the Rule has no recordkeeping requirement and records relating to customer communications already must be made and retained pursuant to other SEC rules); (b) the summary fashion in which information must be provided to customers in the privacy and opt out notices required by the Rule (the model privacy form adopted by the SEC and the other agencies in 2009, designed to serve as both a privacy notice and an opt out notice, is only two pages); (c) the availability to covered entities of the model privacy form and online model privacy form builder; and (d) the experience of covered entities' staff with the notices, SEC staff estimates that covered entities will each spend an average of approximately 12 hours per year complying with the Rule, for a total of approximately 262,500 annual burden hours ($12 \times 21{,}875 = 262{,}500$). SEC staff understands that the vast majority of covered entities deliver their privacy and opt out notices with other communications such as account opening documents and account statements. Because the other communications are already delivered to consumers, adding a brief privacy and opt out notice should not result in added costs for processing or for postage and materials. Also, privacy and opt out notices may be delivered electronically to consumers who have agreed to electronic communications, which further reduces the costs of delivery. Because SEC staff assumes that most paper copies of privacy and opt out notices are combined with other required mailings, the burden-hour estimates above are based on resources required to integrate the privacy and opt notices into another mailing, rather than on the resources required to create and send a separate mailing. SEC staff estimates that, of the estimated 12 annual burden hours incurred, approximately 8 hours would be spent by administrative assistants at an hourly rate of $83, and approximately 4 hours would be spent by internal counsel at an hourly rate of $428, for a total annual internal cost of compliance of approximately $2,376 for each of the covered entities ($8 \times \$83 = \$664$; $4 \times \$428 = \$1{,}712$; $\$664 + \$1{,}712 = \$2{,}376$). Hourly cost of compliance estimates for

administrative assistant time are derived from the Securities Industry and Financial Markets Association's *Office Salaries in the Securities Industry 2013,* modified by SEC staff to account for an 1,800-hour work-year and multiplied by 2.93 to account for bonuses, firm size, employee benefits and overhead. Hourly cost of compliance estimates for internal counsel time are derived from the Securities Industry and Financial Markets Association's *Management & Professional Earnings in the Securities Industry 2013,* modified by SEC staff to account for an 1,800-hour work-year and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead. Accordingly, SEC staff estimates that the total annual internal cost of compliance for the estimated total hour burden for the approximately 21,875 covered entities subject to the Rule is approximately $51,975,000 ($2,376 × 21,875 = $51,975,000).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: >*www.reginfo.gov*<. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) >w*ww.reginfo.gov/public/do/PRAMain*< and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: P*RA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24140 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–475, OMB Control No. 3235–0536]

Proposed Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Regulation FD

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Regulation FD (17 CFR 243.100 *et seq.*)—Other Disclosure Materials requires public disclosure of material information from issuers of publicly traded securities so that investors have current information upon which to base investment decisions. The purpose of the regulation is to require: (1) An issuer that intentionally discloses material information, to do so through public disclosure, not selective disclosure; and (2) to make prompt public disclosure of material information that was unintentionally selectively disclosed. We estimate that approximately 13,000 issuers make Regulation FD disclosures approximately five times a year for a total of 58,000 submissions annually, not including an estimated 7,000 issuers who file Form 8–K to comply with Regulation FD. We estimate that it takes 5 hours per response (58,000 responses × 5 hours) for a total burden of 290,000 hours annually. In addition, we estimate that 25% of the 5 hours per response (1.25 hours) is prepared by the filer for an annual reporting burden of 72,500 hours (1.25 hours per response × 58,000 responses).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

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 control number.

Please direct your written comment to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24130 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–377, OMB Control No. 3235–0425]

Proposed Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Form TH

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form TH (17 CFR 239.65, 17 CFR 249.447, 269.10 and 17 CFR 274.404) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*), the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), the Trust Indenture Act of 1939 (15 U.S.C. 77aaa *et seq.*) and the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) is used by registrants to notify the Commission that an electronic filer is relying on the temporary hardship exemption for the filing of a document in paper form that would otherwise be required to be filed electronically as required by Rule 201(a) of Regulation S–T. Form TH must be filed every time an electronic filer experiences unanticipated technical difficulties preventing the timely preparation and submission of a required electronic filing. Approximately 5 registrants file Form TH and it takes an estimated 0.33 hours per response for a total annual burden of 2 hours (0.33 hours per response × 5 responses).

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 control number.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comment to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street, NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24135 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–251, OMB Control No. 3235–0256]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Form F–3

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form F–3 (17 CFR 239.33) is used by foreign issuers to register securities pursuant to the Securities Act of 1933 (15 U.S.C. 77a *et seq.*). The information collected is intended to ensure that the information required to be filed by the Commission permits verification of compliance with securities law requirements and assures the public availability of such information. Form F–3 takes approximately 157.84 hours per response and is filed by approximately 113 respondents. We estimate that 25% of the 157.84 hours per response (39.46 hours) is prepared by the registrant for a total annual reporting burden of 4,459 hours (39.46 hours per response × 113 responses).

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 control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24142 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–433, OMB Control No. 3235–0489]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 17a–6

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information provided for in Rule 17a–6 (17 CFR 240.17a–6) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 17a–6 permits national securities exchanges, national securities associations, registered clearing agencies, and the Municipal Securities Rulemaking Board (''MSRB'') (collectively, ''SROs'') to destroy or convert to microfilm or other recording media records maintained under Rule 17a–1, if they have filed a record destruction plan with the Commission and the Commission has declared such plan effective.

There are currently 35 SROs: 24 national securities exchanges, 1 national securities association, the MSRB, and 9 registered clearing agencies. Of the 35 SROs, only 2 SRO respondents have filed a record destruction plan with the Commission. The staff calculates that the preparation and filing of a new record destruction plan should take 160 hours. Further, any existing SRO record destruction plans may require revision, over time, in response to, for example, changes in document retention technology, which the Commission estimates will take much less than the 160 hours estimated for a new plan. The Commission estimates that each SRO that has filed a destruction plan will spend approximately 30 hours per year making required revisions. Thus, the total annual time burden is estimated to be approximately 60 hours per year based on two respondents (30 × 2). The approximate internal compliance cost per hour is $428, resulting in a total internal cost of compliance for these respondents of approximately $25,680 per year (60 hours at $428 per hour).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24134 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–199, OMB Control No. 3235–0199]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 17a–5(c)

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17a–5(c) (17 CFR 240.17a–5(c)), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17a–5(c) generally requires broker-dealers who carry customer accounts to provide statements of the broker-dealer's financial condition to their customers. Paragraph (c)(5) of Rule 17a–5 provides a conditional exemption from this requirement. A broker-dealer that elects to take advantage of the exemption must publish its statements on its website in a prescribed manner, and must maintain a toll-free number that customers can call to request a copy of the statements.

The purpose of the Rule is to ensure that customers of broker-dealers are provided with information concerning the financial condition of the firm that may be holding the customers' cash and securities. The Commission, when adopting the Rule in 1972, stated that the goal was to ''directly'' send a customer essential information so that the customer could ''judge whether his broker or dealer is financially sound.'' The Commission adopted the Rule in response to the failure of several broker-dealers holding customer funds and securities in the period between 1968 and 1971.

The Commission estimates that approximately 163 broker-dealer respondents carrying approximately 186 million public customer accounts incur a burden of approximately 228,024 hours per year to comply with the Rule.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 1, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24137 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34412; 812–15135]

Blackstone/GSO Floating Rate Enhanced Income Fund, et al.

November 1, 2021.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application for an order under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit business development companies (''BDCs'') and closed-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment funds and accounts.

APPLICANTS: Blackstone/GSO Floating Rate Enhanced Income Fund (''BGFLX''); Blackstone Long-Short Credit Income Fund (''BGX''); Blackstone Private Credit Fund (''BCRED''); Blackstone Senior Floating Rate Term Fund (''BSL''); Blackstone Strategic Credit Fund (''BGB''); Blackstone Secured Lending Fund (''BGSL,'' and together with BGFLX, BGX, BSL and BGB, the ''Blackstone Credit Regulated Funds''); Blackstone Liquid Credit Strategies LLC (''BLCS''), the investment adviser to BGFLX, BGX, BSL and BGB; Blackstone Credit BDC Advisors LLC (''BCBA''), the investment adviser to BCRED and BGSL; the investment advisers set forth in Schedule A to the application (together with BLCS and BCBA, the ''Blackstone Credit Advisers''); and the Existing Affiliated Funds set forth on Schedule A to the application.[1]

FILING DATES: The application was filed on June 16, 2020, and amended on February 22, 2021 and July 16, 2021.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary *Secretarys-Office@sec.gov* and serving applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on November 26, 2021, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Rajib Chanda at *Rajib.Chanda@stblaw.com* and Christopher Healey at *Christopher.Healey@stblaw.com.*

FOR FURTHER INFORMATION CONTACT: Joseph Toner, Senior Counsel, at (202) 551–7595 or Marc Mehrespand, Branch Chief, at (202) 551–6825 (Chief Counsel's Office, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application

[1] The Existing Affiliated Funds are entities (i) whose primary investment adviser or sub-adviser is an Adviser (as defined below)(when the sub-adviser is an Adviser, the primary adviser is a Primary Adviser (as defined below)) (ii) that either (A) would be an investment company but for section 3(c)(1), 3(c)(5)(C) or 3(c)(7) of the Act or (B) relies on the rule 3a–7 exemption thereunder from investment company status.

may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. BGFLX, BGX, BSL and BGB, each a Delaware statutory trust, are externally managed, diversified, closed-end management investment companies. Each of BGFLX's and BGX's investment objective is to provide current income, with a secondary objective of capital appreciation. Each of BSL's and BGB's investment objective is to seek high current income, with a secondary objective to seek preservation of capital, consistent with its primary goal of high current income. Each of BGFLX, BGX, BSL and BGB has a five-member Board, of which four members are Non-Interested Trustees.[2]

2. BCRED is a Delaware statutory trust that has elected to be regulated as a business development company (''BDC'') under the Act.[3] BCRED's investment objective is to generate current income and, to a lesser extent, generate long-term capital appreciation. BCRED has a six-member Board, of which four members are Non-Interested Trustees.

3. BGSL is a Delaware statutory trust that has elected to be regulated as a BDC. BGSL's investment objective is to generate current income and, to a lesser extent, long-term capital appreciation. BGSL has a seven-member Board, of which four members are Non-Interested Trustees.

4. Each of the Advisers[4] is a subsidiary of The Blackstone Group, Inc. (''Blackstone''). Blackstone is a leading global alternative asset manager, whose alternative asset management businesses include investment entities focused on private equity, real estate, hedge fund solutions, non-investment grade credit, secondary private equity funds of funds and multi-asset class strategies. Blackstone's four business segments are (1) private equity, (2) real estate, (3) hedge fund solutions and (4) credit.

5. The Blackstone Credit Advisers operate as a self-contained advisory business within Blackstone's credit group. Each Blackstone Credit Adviser is under common control with BLCS and BCBA, the Adviser to each of the Blackstone Credit Regulated Funds, and collectively they conduct a single advisory business for purposes of the requested order. The Blackstone Credit Advisers are each either separately registered as investment advisers with the Commission or are relying advisers that rely on the registration of another Blackstone Credit Adviser. No Blackstone Credit Adviser is a relying adviser of any Blackstone-affiliated investment adviser from outside of the self-contained group.

6. Applicants seek an order to permit one or more Regulated Funds[5] to be able to participate with one or more other Regulated Funds and/or one or more Affiliated Investors[6] in the same investment opportunities through a proposed co-investment program where such participation would otherwise be prohibited under sections 17(d) and 57(a)(4) of the Act and the rules thereunder (the ''Co-Investment Program'').

7. For purposes of the requested order, ''Co-Investment Transaction'' means any transaction in which one or more Regulated Funds (or one or more Wholly-Owned Investment Subsidiaries, as defined below) participates together with one or more other Regulated Funds (or one or more Wholly-Owned Investment Subsidiaries) and/or one or more Affiliated Investors in reliance on the requested order. ''Potential Co-Investment Transaction'' means any investment opportunity in which a Regulated Fund (or its Wholly-Owned Investment Subsidiary, as defined below) could not participate together with one or more Affiliated Investors and/or one or more other Regulated Funds without obtaining and relying on the requested order.[7] Funds that are advised or sub-advised by affiliates of Blackstone other than an Adviser or Primary Adviser will not participate in the Co-Investment Program. No Primary Adviser will be the source of any Potential Co-Investment Transactions under the requested order. Potential Co-Investment Transactions will not be shared outside of the Co-Investment Program.

8. Applicants state that a Regulated Fund may, from time to time, form one or more Wholly-Owned Investment

[2] ''Board'' means the board of trustees (or equivalent) of a Regulated Fund (as defined below). ''Non-Interested Trustees'' are not ''interested persons'' as defined in section 2(a)(19) of the Act.

[3] Section 2(a)(48) of the Act defines a BDC to be any closed-end investment company that operates for the purpose of making investments in securities described in sections 55(a)(1) through 55(a)(3) of the Act and makes available significant managerial assistance with respect to the issuers of such securities.

[4] The term ''Adviser'' means the Blackstone Credit Advisers and any future investment adviser that (i) controls, is controlled by or is under common control with a Blackstone Credit Adviser, (ii) is registered as an investment adviser under the Advisers Act, and (iii) that intends to participate in the Co-Investment Program (as defined below). The term ''Primary Adviser'' means any future or existing investment adviser that (i) controls, is controlled by or is under common control with an Adviser, (ii) is registered as an investment adviser under the Advisers Act, and (iii) is not an Adviser under the requested order. For the avoidance of doubt, a Primary Adviser will not be treated as an Adviser under the requested order, but will be subject to conditions 2(c)(iv) and 15 only. No Primary Adviser will rely on the requested order with respect to any investment entities it manages other than to the extent those entities are sub-advised by an Adviser. No Primary Adviser will be the source of any Potential Co-Investment Transactions (as defined below) under the requested order.

[5] ''Regulated Fund'' means (i) the Blackstone Credit Regulated Funds and (ii) and any Future Regulated Fund (as defined below). ''Future Regulated Fund'' means any future closed-end management investment company (i) that has elected to be regulated as a BDC or is registered under the Act, (ii) whose investment adviser is an Adviser and (iii) who intends to participate in the Co-Investment Program.

[6] ''Affiliated Investor'' means (i) the Existing Affiliated Funds, (ii) any Affiliated Proprietary Account and (iii) any Future Affiliated Fund (as defined below). Affiliated Investors may include funds that are ultimately structured as collateralized loan obligation funds (''CLOs''). Such CLOs would be investment companies but for the exception in section 3(c)(7) of the Act or their ability to rely on rule 3a–7 thereunder. During the investment period of a CLO, the CLO may engage in certain transactions customary in CLO formations with another Affiliated Investor on a secondary basis at fair market value. For purposes of the requested order, any securities that were acquired by an Affiliated Investor in a particular Co-Investment Transaction that are then transferred in such customary transactions to an Affiliated Investor that is or will become a CLO (an ''Affiliated Fund CLO'') will be treated as if the Affiliated Fund CLO acquired such securities in the Co-Investment Transaction. For the avoidance of doubt, any such transfer from an Affiliated Investor to an Affiliated Fund CLO will be treated as a Disposition (as defined below) and completed pursuant to the terms and conditions of the application, though the applicants note that the Regulated Funds would be prohibited from participating in such Disposition by section 17(a)(2) or section 57(a)(2) of the Act, as applicable. The participation by any Affiliated Fund CLO in any such Co-Investment Transaction will remain subject to the requested order.

''Future Affiliated Fund'' means an entity (i)(A) whose investment adviser is an Adviser or (B) whose investment adviser is a Primary Adviser and whose sub-adviser is an Adviser, (ii) that either (A) would be an investment company but for an exemption in section 3(c)(1), 3(c)(5)(C) or 3(c)(7) of the Act or (B) relies on the rule 3a–7 exemption from investment company status, and (iii) that intends to participate in the Co-Investment Program.

''Affiliated Proprietary Account'' means any account of an Adviser or its affiliates or any company that is an indirect, wholly- or majority-owned subsidiary of an Adviser or its affiliates, which, from time to time, may hold various financial assets in a principal capacity. For the avoidance of doubt, neither the Regulated Funds, the Existing Affiliated Funds nor any Future Affiliated Fund shall be deemed to be Affiliated Proprietary Accounts for purposes of the application.

[7] All existing entities that currently intend to rely upon the requested order have been named as applicants. Any other existing or future entity that subsequently relies on the requested order will comply with the terms and conditions of the application.

Subsidiaries.[8] A Wholly-Owned Investment Subsidiary would be prohibited from investing in a Co-Investment Transaction with another Regulated Fund or any Affiliated Investor because it would be a company controlled by the applicable Regulated Fund for purposes of sections 17(d) and 57(a)(4) of the Act and rule 17d–1 thereunder. Applicants request that a Wholly-Owned Investment Subsidiary be permitted to participate in Co-Investment Transactions in lieu of the applicable Regulated Fund and that the Wholly-Owned Investment Subsidiary's participation in any such transaction be treated, for purposes of the requested order, as though the Regulated Fund were participating directly.

9. When considering Potential Co-Investment Transactions for any Regulated Fund, an Adviser will consider only the Objectives and Strategies,[9] Board-Established Criteria,[10] investment policies, investment positions, capital available for investment, and other pertinent factors applicable to that Regulated Fund. The participation of a Regulated Fund in a Potential Co-Investment Transaction may only be approved by a Required Majority, as defined in section 57(o) of the Act (a ''Required Majority''), of the trustees of the Board eligible to vote on that Co-Investment Transaction under section 57(o) of the Act (the ''Eligible Trustees'').[11] When selecting investments for the Affiliated Investors, an Adviser will select investments separately for each Affiliated Investor, considering, in each case, only the investment objective, investment policies, investment position, capital available for investment, and other pertinent factors applicable to that particular Affiliated Investor.

10. With respect to participation in a Potential Co-Investment Transaction by a Regulated Fund, the applicable Adviser will present each Potential Co-Investment Transaction and the proposed allocation of each investment opportunity to the Eligible Trustees. The Required Majority of a Regulated Fund will approve each Co-Investment Transaction prior to any investment by the Regulated Fund.

11. Applicants state that the majority of the Blackstone Credit Advisers' employees work on matters for Close Affiliates[12] and information about potential investment opportunities is routinely disseminated among such Adviser's employees. Other than to satisfy compliance obligations, information regarding Potential Co-Investment Transactions will not be shared with Remote Affiliates,[13] which would include other investment advisers that operate in other Blackstone business groups, except in unusual circumstances, as the Blackstone business groups each generally target different investment strategies or asset classes and there are information barrier policies in place between the Blackstone business groups. Applicants further note that within the Blackstone Credit Advisers, the personnel overlap and coordination among portfolio management teams ensures that all relevant investment opportunities will be brought to the attention of each Regulated Fund managed by the respective Adviser. Applicants submit that the Blackstone Credit Advisers will receive all information regarding all investment opportunities that fall within the then-current Objectives and Strategies and Board-Established Criteria of each Regulated Fund managed by the respective Adviser, regardless of whether the Adviser serves as the primary investment adviser or sub-adviser to the Regulated Fund.

12. Applicants acknowledge that some of the Affiliated Investors may not be funds advised by an Adviser because they are Affiliated Proprietary Accounts. Applicants do not believe these Affiliated Proprietary Accounts should raise issues under the conditions of the requested order because allocation policies and procedures of the account owners provide that investment opportunities are offered to client accounts before they are offered to Affiliated Proprietary Accounts.

13. Applicants represent that the Co-Investment Program requires that the terms, conditions, price, class of securities, settlement date, and registration rights applicable to a Regulated Fund's purchase be the same as those applicable to the purchase by the other participating Regulated Funds and Affiliated Investors. However, the settlement date for an Affiliated Investor in a Co-Investment Transaction may occur up to ten business days after the settlement date for the Regulated Fund, and vice versa. Nevertheless, in all cases (i) the date on which the commitment of the Affiliated Investors and Regulated Funds is made will be the same even where the settlement date is not and (ii) the earliest settlement date and the latest settlement date of any Affiliated Investor or Regulated Fund participating in the transaction will occur within ten business days of each other.

14. Under condition 16, if an Adviser or its principals, or any person controlling, controlled by, or under

[8] ''Wholly-Owned Investment Subsidiary'' means an entity (i) whose sole business purpose is to hold one or more investments on behalf of a Regulated Fund (and, in the case of an SBIC Subsidiary (as defined below), maintain a license under the SBA Act (as defined below) and issue debentures guaranteed by the SBA (as defined below)); (ii) that is a wholly-owned subsidiary (as defined in the Act) of a Regulated Fund (with such Regulated Fund at all times holding, beneficially and of record, 95% or more of the voting and economic interests); (iii) with respect to which the Board of the Regulated Fund has the sole authority to make all determinations with respect to the Wholly-Owned Investment Subsidiary's participation under the conditions of the requested order; and (iv) that is an entity that would be an investment company but for an exemption in section 3(c)(1) or 3(c)(7) of the Act.

The term ''SBIC Subsidiary'' means a Wholly-Owned Investment Subsidiary that is licensed by the Small Business Administration (the ''SBA'') to operate under the Small Business Investment Act of 1958, as amended, (the ''SBA Act'') as a small business investment company (a ''SBIC'').

[9] The term ''Objectives and Strategies'' means a Regulated Fund's investment objectives and strategies, as described in the filings made with the Commission by the Regulated Fund under the Securities Exchange Act of 1934, as amended, the Securities Act of 1933, as amended (the ''1933 Act'') and the Act, and the Regulated Fund's reports to shareholders.

[10] The term ''Board-Established Criteria'' means criteria that the Board of the applicable Regulated Fund may establish from time to time to describe the characteristics of Potential Co-Investment Transactions regarding which an Adviser to the Regulated Fund should be notified under condition 1 of the requested order. The Board-Established Criteria will be consistent with the Regulated Fund's then-current Objectives and Strategies. If no Board-Established Criteria are in effect, then the Regulated Fund's Adviser will be notified of all Potential Co-Investment Transactions that fall within the Regulated Fund's then current Objectives and Strategies. Board-Established Criteria will be objective and testable, meaning that they will be based on observable information, such as industry/sector of the issuer, minimum earnings before interest, taxes, depreciation, and amortization of the issuer, asset class of the investment opportunity or required commitment size, and not on characteristics that involve discretionary assessment. The Adviser to the Regulated Fund may from time to time recommend criteria for the applicable Board's consideration, but Board-Established Criteria will only become effective if approved by a majority of the Non-Interested Trustees. The Non-Interested Trustees of a Regulated Fund may at any time rescind, suspend or qualify its approval of any Board-Established Criteria, though Applicants anticipate that, under normal circumstances, the Board would not modify these criteria more often than quarterly.

[11] The defined terms Eligible Trustees and Required Majority apply as if each Regulated Fund were a BDC subject to section 57(o) of the Act.

[12] The term ''Close Affiliate'' means the Advisers, the Regulated Funds, the Affiliated Investors and any other person described in section 57(b) of the Act (after giving effect to rule 57b-1 thereunder) in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose) except for limited partners included solely by reason of the reference in section 57(b) to section 2(a)(3)(D) of the Act.

[13] The term ''Remote Affiliate'' means any person described in section 57(e) of the Act in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose) and any limited partner holding 5% or more of the relevant limited partner interests that would be a Close Affiliate but for the exclusion in that definition.

common control with the Adviser or its principal owners, and the Affiliated Investor (collectively, the ''Holders'') own in the aggregate more than 25 percent of the outstanding voting shares of a Regulated Fund (''Shares''), then the Holders will vote such Shares as required under condition 16.

15. No Eligible Trustee will have a direct or indirect financial interest in any Co-Investment Transaction, other than through any interest such Eligible Trustee may have in securities of a Regulated Fund.

Applicants' Legal Analysis

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit affiliated persons of a registered investment company from participating in joint transactions with the company unless the Commission has granted an order permitting such transactions. In passing upon applications under rule 17d–1, the Commission considers whether the company's participation in the joint transaction is consistent with the provisions, policies, and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of other participants.

2. Section 57(a)(4) of the Act prohibits certain affiliated persons of a BDC from participating in joint transactions with the BDC or a company controlled by a BDC in contravention of rules as prescribed by the Commission. Under section 57(b)(2) of the Act, any person who is directly or indirectly controlling, controlled by, or under common control with a BDC is subject to section 57(a)(4) of the Act. Section 57(i) of the Act provides that, until the Commission prescribes rules under section 57(a)(4) of the Act, the Commission's rules under section 17(d) of the Act applicable to registered closed-end investment companies will be deemed to apply to transactions subject to section 57(a)(4) of the Act. Because the Commission has not adopted any rules under section 57(a)(4) of the Act, rule 17d–1 thereunder applies.

3. Applicants state that certain transactions effected as part of the Co-Investment Program may be prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 thereunder without a prior exemptive order of the Commission to the extent that the Affiliated Investors fall within the category of persons described by section 17(d) or section 57(b) of the Act, as modified by rule 57b–1 thereunder with respect to a Regulated Fund. Applicants believe that the proposed terms and conditions will ensure would ensure that the conflicts of interest that section 17(d) and section 57(a)(4) of the Act were designed to prevent would be addressed and the standards for an order under rule 17d–1 under the Act are met.

Applicants' Conditions

Applicants agree that any order granting the requested relief shall be subject to the following conditions:

1. (a) Each Adviser will establish, maintain and implement policies and procedures reasonably designed to ensure that each Adviser is promptly notified, for each Regulated Fund the Adviser manages, of all Potential Co-Investment Transactions [14] that (i) an Adviser considers for any other Regulated Fund or Affiliated Investor and (ii) fall within the Regulated Fund's then-current Objectives and Strategies and Board-Established Criteria.

(b) When an Adviser to a Regulated Fund is notified of a Potential Co-Investment Transaction under condition 1(a), such Adviser will make an independent determination of the appropriateness of the investment for the Regulated Fund in light of the Regulated Fund's then-current circumstances.

2. (a) If the Adviser deems a Regulated Fund's participation in any Potential Co-Investment Transaction to be appropriate for the Regulated Fund, it will then determine an appropriate level of investment for the Regulated Fund.

(b) If the aggregate amount recommended by the applicable Adviser to be invested by the applicable Regulated Fund in the Potential Co-Investment Transaction, together with the amount proposed to be invested by the other participating Regulated Funds and Affiliated Investors, collectively, in the same transaction, exceeds the amount of the investment opportunity, then the investment opportunity will be allocated among them pro rata based on each participant's Available Capital [15] up to the amount proposed to be invested by each. The applicable Adviser will provide the Eligible Trustees of each participating Regulated Fund with information concerning each participating party's Available Capital to assist the Eligible Trustees with their review of the Regulated Fund's investments for compliance with these allocation procedures.

(c) After making the determinations required in conditions 1 and 2(a), the applicable Adviser will distribute written information concerning the Potential Co-Investment Transaction (including the amount proposed to be invested by each participating Regulated Fund and Affiliated Investor) to the Eligible Trustees of each participating Regulated Fund for their consideration. A Regulated Fund will co-invest with one or more other Regulated Funds and/or one or more Affiliated Investors only if, prior to the Regulated Fund's participation in the Potential Co-Investment Transaction, a Required Majority concludes that:

(i) The terms of the Potential Co-Investment Transaction, including the consideration to be paid, are reasonable and fair to the Regulated Fund and its shareholders and do not involve overreaching in respect of the Regulated Fund or its shareholders on the part of any person concerned;

(ii) The Potential Co-Investment Transaction is consistent with:

(A) The interests of the shareholders of the Regulated Fund; and

(B) the Regulated Fund's then-current Objectives and Strategies;

(iii) the investment by any other Regulated Funds or Affiliated Investors would not disadvantage the Regulated Fund, and participation by the Regulated Fund would not be on a basis different from or less advantageous than that of other Regulated Funds or Affiliated Investors; provided that, if any other Regulated Fund or Affiliated Investor, but not the Regulated Fund itself, gains the right to nominate a director for election to a portfolio company's board of directors or the right to have a board observer or any similar right to participate in the governance or management of the portfolio company, such event shall not be interpreted to prohibit the Required Majority from reaching the conclusions required by this condition (2)(c)(iii), if:

(A) The settlement date for another Regulated Fund or an Affiliated Investor in a Co-Investment Transaction is later

[14] No Primary Adviser will be the source of any Potential Co-Investment Transactions under the requested order.

[15] ''Available Capital'' means (a) for each Regulated Fund, the amount of capital available for investment determined based on the amount of cash on hand, liquidity considerations, existing commitments and reserves, if any, the targeted leverage level, targeted asset mix, risk-return and target-return profile, tax implications, regulatory or contractual restrictions or consequences, and other investment policies and restrictions set from time to time by the Board of the applicable Regulated Fund or imposed by applicable laws, rules, regulations or interpretations, and (b) for each Affiliated Investor, the amount of capital available for investment determined based on the amount of cash on hand, liquidity considerations, existing commitments and reserves, if any, the targeted leverage level, targeted asset mix, risk-return and target-return profile, tax implications, regulatory or contractual restrictions or consequences and other investment policies and restrictions set from time to time by the Affiliated Investors' trustees, general partners, or adviser or imposed by applicable laws, rules, regulations or interpretations.

than the settlement date for the Regulated Fund by no more than ten business days or earlier than the settlement date for the Regulated Fund by no more than ten business days, in either case, so long as: (x) The date on which the commitment of the Affiliated Investors and Regulated Funds is made is the same; and (y) the earliest settlement date and the latest settlement date of any Affiliated Investor or Regulated Fund participating in the transaction will occur within ten business days of each other;

(B) the Eligible Trustees will have the right to ratify the selection of such director or board observer, if any;

(C) the applicable Adviser agrees to, and does, provide periodic reports to the Regulated Fund's Board with respect to the actions of such director or the information received by such board observer or obtained through the exercise of any similar right to participate in the governance or management of the portfolio company; and

(D) any fees or other compensation that any Affiliated Investor or any Regulated Fund or any affiliated person of any Affiliated Investor or any Regulated Fund receives in connection with the right of an Affiliated Investor or a Regulated Fund to nominate a director or appoint a board observer or otherwise to participate in the governance or management of the portfolio company will be shared proportionately among the participating Affiliated Investors (who each may, in turn, share its portion with its affiliated persons), and the participating Regulated Funds in accordance with the amount of each party's investment; and

(iv) the proposed investment by the Regulated Fund will not benefit the Advisers, the Affiliated Investors, the other Regulated Funds or any Primary Adviser or any affiliated person of any of them (other than the parties to the Co-Investment Transaction), except

(A) to the extent permitted by condition 15;

(B) to the extent permitted by section 17(e) or 57(k) of the Act, as applicable;

(C) indirectly, as a result of an interest in the securities issued by one of the parties to the Co-Investment Transaction; or

(D) in the case of fees or other compensation described in condition 2(c)(iii)(D).

3. Each Regulated Fund has the right to decline to participate in any Potential Co-Investment Transaction or to invest less than the amount proposed.

4. The applicable Adviser will present to the Board of each Regulated Fund, on a quarterly basis, a record of all investments in Potential Co-Investment Transactions made by any of the other Regulated Funds or Affiliated Investors during the preceding quarter that fell within the Regulated Fund's then-current Objectives and Strategies and Board Established Criteria that were not made available to the Regulated Fund, and an explanation of why the investment opportunities were not offered to the Regulated Fund. All information presented to the Board pursuant to this condition will be kept for the life of the Regulated Fund and at least two years thereafter, and will be subject to examination by the Commission and its staff.

5. Except for Follow-On Investments [16] made in accordance with condition 9 and 10,[17] a Regulated Fund will not invest in reliance on the Order in any issuer in which a Related Party [18] has an investment. The Adviser will maintain books and records that demonstrate compliance with this condition for each Regulated Fund.

6. A Regulated Fund will not participate in any Potential Co-Investment Transaction unless (i) the terms, conditions, price, class of securities to be purchased, registration rights and the date on which the commitment is entered into will be the same for each participating Regulated Fund and Affiliated Investor and (ii) the earliest settlement date and the latest settlement date of any participating Regulated Fund or Affiliated Investor will occur as close in time as practicable and in no event more than ten business days apart. The grant to an Affiliated Investor or another Regulated Fund, but not the Regulated Fund, of the right to nominate a director for election to a portfolio company's board of directors, the right to have an observer on the board of directors or similar rights to participate in the governance or management of the portfolio company will not be interpreted so as to violate this condition 6, if conditions 2(c)(iii)(B), (C), and (D) are met.

7. Standard Review Dispositions.

(a) If any Regulated Fund or Affiliated Investor elects to sell, exchange or otherwise dispose of an interest in a security and one or more Regulated Funds and Affiliated Investors have previously participated in a Co-Investment Transaction with respect to the issuer, then:

(i) The Adviser to such Regulated Fund or Affiliated Investor will notify each Regulated Fund that holds an investment in the issuer of the proposed disposition at the earliest practical time; [19] and

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the disposition.

(b) Each Regulated Fund will have the right to participate in such Disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to the Affiliated Investors and any other Regulated Fund.

(c) A Regulated Fund may participate in such a disposition without obtaining prior approval of the Required Majority if: (i) (A) The participation of each Regulated Fund and Affiliated Investor in such disposition is proportionate to its then-current holding of the security (or securities) of the issuer that is (or are) the subject of the disposition; [20] (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in such dispositions on a pro rata basis (as described in greater detail in the application); and (C) the Board of the Regulated Fund is provided on a quarterly basis with a list of all dispositions made in accordance with this condition; or (ii) each security is a Tradable Security [21] and (A) the disposition is not to the issuer or any affiliated person of the issuer and (B) the security is sold for cash in a transaction in which the only term

[16] ''Follow-On Investment'' means any additional investment in an existing portfolio company whose securities were acquired in a Co-Investment Transaction, including the exercise of warrants, conversion privileges or other similar rights to acquired additional securities of the portfolio company.

[17] This exception applies only to Follow-On Investments by a Regulated Fund in issuers in which that Regulated Fund already holds investments.

[18] The term ''Related Party'' means (i) any Close Affiliate and (ii) in respect of matters as to which any Adviser has knowledge, any Remote Affiliate.

[19] Any Affiliated Proprietary Account that is not advised by an adviser is itself deemed to be an Adviser for purposes of conditions 7(a)(i), 8(a)(i), 9(a)(i) and 10(a)(i).

[20] In the case of any disposition, proportionality will be measured by each participating Regulated Fund's and Affiliated Investor's outstanding investment in the security in question immediately preceding the disposition.

[21] The term ''Tradable Security'' means a security that (i) trades on a national securities exchange or designated offshore securities market as defined in rule 902(b) under the 1933 Act; (ii) is not subject to restrictive agreements with the issuer or other security holders; and (iii) trades with sufficient volume and liquidity (findings as to which are documented by the Advisers to any Regulated Funds holding investments in the issuer and retained for the life of the Regulated Fund) to allow each Regulated Fund to dispose of its entire position remaining after the proposed disposition within a short period of time not exceeding 30 days at approximately the value (as defined by section 2(a)(41) of the Act) at which the Regulated Fund has valued the investment.

negotiated by or on behalf of the participating Regulated Funds and Affiliated Investors is price.

(d) In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Trustees, and the Regulated Fund will participate in such disposition solely to the extent that a Required Majority determines that it is in the Regulated Fund's best interests. Each Affiliated Investor and each Regulated Fund will bear its own expenses in connection with any such disposition.

8. Enhanced Review Dispositions.

(a) If any Regulated Fund or Affiliated Investor elects to sell, exchange or otherwise dispose of a Pre-Boarding Investment [22] in a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Investors have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to such Regulated Fund or Affiliated Investor will notify each Regulated Fund that holds an investment in the issuer of the proposed disposition at the earliest practical time;

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the disposition; and

(iii) the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Investors, including the terms of such investments and how they were made, that is necessary for the Required Majority to make the findings required by this condition.

(b) The Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Trustees, and the Regulated Fund will participate in such disposition solely to the extent that a Required Majority determines that:

(i) The disposition complies with condition 2(c)(i), (ii), (iii)(A) and (iv); and

(ii) the making and holding of the Pre-Boarding Investments were not prohibited by section 57 or rule 17d–1, as applicable, and records the basis for the finding in the Board minutes.

(c) The disposition may only be completed in reliance on the order if:

(i) Each Regulated Fund has the right to participate in such disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to Affiliated Investors and any other Regulated Fund.

(ii) All of the Affiliated Investors' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(iii) Independent counsel to the Board advises that the making and holding of the investments in the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b–1) or rule 17d–1, as applicable;

(iv) all Regulated Funds and Affiliated Investors that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Investors hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the Order, the Required Majority is presented with all information necessary to make a finding, and finds, that: (A) Any Regulated Fund's or Affiliated Investor's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial [23] in amount, including immaterial relative to the size of the issuer; and (B) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date, currency, or denominations may be treated as the same security; and

(d) The Affiliated Investors, the other Regulated Funds and their affiliated persons (within the meaning of section 2(a)(3)(C) of the Act), individually or in the aggregate, do not control the issuer of the securities (within the meaning of section 2(a)(9) of the Act).

9. Standard Review Follow-Ons.

(a) If any Regulated Fund or Affiliated Investor desires to make a Follow-On Investment in an issuer and the Regulated Funds and Affiliated Investors holding investments in the issuer previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to each such Regulated Fund or Affiliated Investor will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time; and

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund.

(b) A Regulated Fund may participate in the Follow-On Investment without obtaining prior approval of the Required Majority if: (i)(A) The proposed participation of each Regulated Fund and each Affiliated Investor in such investment is proportionate to its outstanding investments in the issuer or the security at issue, as appropriate,[24] immediately preceding the Follow-On Investment; and (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in Follow-On Investments on a pro rata basis (as described in greater detail in the application); or (ii) it is a Non-Negotiated Follow-On Investment.[25]

(c) In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Trustees, and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority makes the

[22] The term ''Pre-Boarding Investments'' means any investment in an issuer that is (i) held by a Regulated Fund as well as one or more Affiliated Investors and/or one or more other Regulated Funds, (ii) acquired prior to participating in any Co-Investment Transaction, and (iii) acquired (A) in a transaction in which the only term negotiated by or on behalf of such funds was price in reliance on one of the Joint Transaction No-Action Letters; or (B) in transactions occurring at least 90 days apart and without coordination between the Regulated Fund and any Affiliated Investor or other Regulated Fund. The ''Joint Transaction No-Action Letters'' are *SMC Capital, Inc.,* SEC Staff No-Action Letter (Sept. 5, 1995) and *Massachusetts Mutual Life Insurance Company,* SEC Staff No-Action Letter (June 7, 2000).

[23] In determining whether a holding is ''immaterial'' for purposes of the requested order, the Required Majority will consider whether the nature and extent of the interest in the transaction or arrangement is sufficiently small that a reasonable person would not believe that the interest affect the determination of whether to enter into the transaction or arrangement or the terms of the transaction or arrangement.

[24] To the extent that a Follow-On Investment opportunity is in a security or arises in respect of a security held by the participating Regulated Funds and Affiliated Investors, proportionality will be measured by each participating Regulated Fund's and Affiliated Investor's outstanding investment in the security in question immediately preceding the Follow-On Investment using the most recent available valuation thereof. To the extent that a Follow-On Investment opportunity relates to an opportunity to invest in a security that is not in respect of any security held by any of the participating Regulated Funds or Affiliated Investors, proportionality will be measured by each participating Regulated Fund's and Affiliated Investor's outstanding investment in the issuer immediately preceding the Follow-On Investment using the most recent available valuation thereof.

[25] The term ''Non-Negotiated Follow-On Investment'' means a Follow-On Investment in which a Regulated Fund participates together with one or more Affiliated Investors and/or one or more other Regulated Funds (i) in which the only term negotiated by or on behalf of the funds is price and (ii) with respect to which, if the transaction were considered on its own, the funds would be entitled to rely on SEC guidance under either of the Joint Transaction No-Action Letters.

determinations set forth in condition 2(c). If the only previous Co-Investment Transaction with respect to the issuer was an Enhanced Review Disposition the Eligible Trustees must complete this review of the proposed Follow-On Investment both on a stand-alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms of the investment.

(d) If, with respect to any such Follow-On Investment:

(i) The amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Investors' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and

(ii) if the aggregate amount recommended by the applicable Adviser to be invested by the applicable Regulated Fund in the Potential Co-Investment Transaction, together with the amount proposed to be invested by the other participating Regulated Funds and Affiliated Investors, collectively, in the same transaction, exceeds the amount of the investment opportunity; then the Follow-On Investment Opportunity will be allocated among them pro rata based on Available Capital (as described in greater detail in the application), up to the amount proposed to be invested by each.

(e) The acquisition of Follow-On Investments as permitted by this condition will be considered a Co-Investment Transaction for all purposes and subject to the other conditions set forth in the application.

10. Enhanced Review Follow-Ons.

(a) If any Regulated Fund or Affiliated Investor desires to make a Follow-On Investment in an issuer that is a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Investor holding investments in the issuer have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to each such Regulated Fund or Affiliated Investor will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time;

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund; and

(iii) the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Investors, including the terms of such investments and how they were made, that is necessary for the Required Majority to make the findings required by this condition.

(b) The applicable Adviser will provide its written recommendation as to a Regulated Fund's participation to the Eligible Trustees, and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority reviews the proposed Follow-On Investment both on a stand-alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms and makes the determinations set forth in condition 2(c). In addition, the Follow-On Investment may only be completed in reliance on the order if the Required Majority of each participating Regulated Fund determines that the making and holding of the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b–1) or rule 17d–1, as applicable. The basis for the Board's findings will be recorded in its minutes.

(c) The Follow-On Investment may only be completed in reliance on the order if:

(i) All of the Affiliated Investors' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(ii) Independent counsel to the Board of each Regulated Fund that holds an investment in the issuer advises that the making and holding of the investments in the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b–1) or rule 17d–1, as applicable;

(iii) All Regulated Funds and Affiliated Investors that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Investors hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the order, the Required Majority is presented with all information necessary to make a finding, and finds, that: (A) Any Regulated Fund's or Affiliated Investor's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial in amount, including immaterial relative to the size of the issuer; and (B) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date, currency or denominations may be treated as the same security; and

(iv) The Affiliated Investors, the other Regulated Funds and their affiliated persons (within the meaning of section 2(a)(3)(C) of the Act), individually or in the aggregate, do not control the issuer of the securities (within the meaning of section 2(a)(9) of the Act).

(d) If, with respect to any such Follow-On Investment:

(i) The amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Investors' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and

(ii) the aggregate amount recommended by the Advisers to be invested in the Follow-On Investment by the participating Regulated Funds and any participating Affiliated Investors, collectively, exceeds the amount of the investment opportunity, then the Follow-On Investment opportunity will be allocated among them pro rata based on Available Capital (as described in greater detail in the application).

(e) Other Conditions. The acquisition of Follow-On Investments as permitted by this condition will be considered a Co-Investment Transaction for all purposes and subject to the other conditions set forth in the application.

11. The Non-Interested Trustees of each Regulated Fund will be provided quarterly for review all information concerning Potential Co-Investment Transactions that fell within the Regulated Fund's then-current Objectives and Strategies and Board-Established Criteria, including investments in Potential Co-Investment Transactions made by other Regulated Funds or Affiliated Investors that the Regulated Fund considered but declined to participate in, and concerning Co-Investment Transactions in which the Regulated Fund participated, so that the Non-Interested Trustees may determine whether all Potential Co-Investment Transactions and Co-Investment Transactions during the preceding quarter, including those Potential Co-Investment Transactions which the Regulated Fund considered but declined to participate in, comply with the conditions of the order. In addition, the Non-Interested Trustees will consider at least annually: (a) The continued appropriateness for the Regulated Fund of participating in new and existing Co-Investment Transactions, and (b) the continued appropriateness of any Board-Established Criteria.

12. Each Regulated Fund will maintain the records required by section 57(f)(3) of the Act as if each of the Regulated Funds were a BDC and each of the investments permitted under these conditions were approved by the Required Majority under section 57(f) of the Act.

13. No Non-Interested Trustee of a Regulated Fund will also be a director, general partner, managing member or principal, or otherwise an ''affiliated person'' (as defined in the Act) of any of the Affiliated Investors.

14. The expenses, if any, associated with acquiring, holding or disposing of any securities acquired in a Co-Investment Transaction (including, without limitation, the expenses of the distribution of any such securities registered for sale under the 1933 Act) will, to the extent not payable by the Advisers under their respective investment advisory agreements with Affiliated Investors and the Regulated Funds, be shared by the Regulated Funds and the Affiliated Investors in proportion to the relative amounts of the securities held or to be acquired or disposed of, as the case may be.

15. Any transaction fee [26] (including break-up, structuring, monitoring or commitment fees but excluding broker's fees contemplated by section 17(e) or 57(k) of the Act, as applicable), received in connection with a Co-Investment Transaction will be distributed to the participating Regulated Funds and Affiliated Investors on a pro rata basis based on the amounts they invested or committed, as the case may be, in such Co-Investment Transaction. If any transaction fee is to be held by an Adviser pending consummation of the transaction, the fee will be deposited into an account maintained by the Adviser at a bank or banks having the qualifications prescribed in section 26(a)(1) of the Act, and the account will earn a competitive rate of interest that will also be divided pro rata among the participating Regulated Funds and Affiliated Investors based on the amount they invest in such Co-Investment Transaction. None of the Advisers, the Primary Advisers, the Affiliated Investors, the other Regulated Funds nor any affiliated person of the Regulated Funds or Affiliated Investors will receive additional compensation or remuneration of any kind as a result of or in connection with a Co-Investment Transaction (other than (a) in the case of the Regulated Funds and the Affiliated Investors, the pro rata transaction fees described above and fees or other compensation described in condition 2(c)(iii)(D), and (b) in the case of an Adviser or Primary Adviser, investment advisory fees paid in accordance with their respective agreements between the Advisers and the Regulated Fund or Affiliated Investor).

16. If the Holders own in the aggregate more than 25% of the Shares, then the Holders will vote such Shares in the same percentages as the Regulated Fund's other shareholders (not including the Holders) when voting on (1) the election of trustees; (2) the removal of one or more trustees; or (3) all other matters under either the Act or applicable state law affecting the Board's composition, size or manner of election.

17. Each Regulated Fund's chief compliance officer, as defined in rule 38a–1(a)(4) under the Act, will prepare an annual report for its Board each year that evaluates (and documents the basis of that evaluation) the Regulated Fund's compliance with the terms and conditions of the application and the procedures established to achieve such compliance.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–24148 Filed 11–4–21; 8:45 am]

BILLING CODE 8011–01–P

[26] Applicants are not requesting and the staff is not providing any relief for transaction fees received in connection with any Co-Investment Transaction.

SURFACE TRANSPORTATION BOARD

[Docket No. EP 670 (Sub–No. 1)]

Notice of Rail Energy Transportation Advisory Committee Meeting

AGENCY: Surface Transportation Board.

ACTION: Notice of Rail Energy Transportation Advisory Committee meeting.

SUMMARY: Notice is hereby given of a meeting of the Rail Energy Transportation Advisory Committee (RETAC), pursuant to the Federal Advisory Committee Act.

DATES: The meeting will be held on Tuesday, November 16, 2021, beginning at 1:00 p.m. E.S.T., and is expected to conclude by 4:00 p.m. E.S.T.

ADDRESSES: The meeting will be held virtually via Zoom. See **SUPPLEMENTARY INFORMATION** for registration details.

FOR FURTHER INFORMATION CONTACT: Kristen Nunnally at (202) 245–0312 or *Kristen.Nunnally@stb.gov.* Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: RETAC was formed in 2007 to provide advice and guidance to the Board, and to serve as a forum for discussion of emerging issues related to the transportation of energy resources by rail. *Establishment of a Rail Energy Transp. Advisory Comm.,* EP 670 (STB served July 17, 2007). The purpose of this meeting is to facilitate discussions regarding issues of interest, including rail service, infrastructure planning and development, and effective coordination among suppliers, rail carriers, and users of energy resources. Agenda items for this meeting may include a rail performance measures review, industry segment updates by RETAC members, and a roundtable discussion.

The meeting, which is open to the public via Zoom, will be conducted in accordance with the Federal Advisory Committee Act, 5 U.S.C. app. 2; Federal Advisory Committee Management regulations, 41 CFR pt. 102–3; the RETAC charter; and Board procedures. Members of the public who wish to attend this meeting must register in advance of the meeting. The registration link will be provided on the Board's website at *https://stb.gov/resources/stakeholder-committees/retac/.* Registrations will be accepted on a space-available basis. Further communications about this meeting may be announced through the Board's website at *www.stb.gov.*

Public Comments: Members of the public may submit written comments to RETAC at any time. Comments should be emailed to Kristen Nunnally, *Kristen.Nunnally@stb.gov,* with RETAC Comments as the subject line.

Authority: 49 U.S.C. 1321, 49 U.S.C. 11101; 49 U.S.C. 11121.

Decided: November 1, 2021.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Tammy Lowery,

Clearance Clerk.

[FR Doc. 2021–24178 Filed 11–4–21; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36546]

325 South Route 31 Railroad, LLC—Operation Exemption—Tracks of 325 South Route 31, LLC in Kendall County, Ill.

325 South Route 31 Railroad, LLC (SRRR), a noncarrier, has filed a verified notice of exemption pursuant to 49 CFR

1150.31 to operate approximately 11,245 feet of track in Kendall County, Ill. (the Line), owned by its parent company, 325 South Route 31, LLC (SR), also a noncarrier. The Line is on a 350-acre industrial site located approximately 40 miles west of Chicago, Ill. (the Site). The Line has no mileposts. According to SRRR, no common carrier services are currently being offered on the Line.

According to the verified notice, SRRR will enter into an agreement with SR that will allow SRRR the rights to lease, operate, and maintain the Line.[1] SRRR states that it intends to rehabilitate some of the existing tracks prior to commencing rail service operations on the Line. SRRR states that, as the Site is being developed and as industries locate on the Line in the short term, a third party will provide switching operations on the Line by contract.[2] SRRR states that it plans to close the transaction on or after the effective date of this exemption.

SRRR states that the proposed operation of the Line does not involve any provision or agreement that would limit future interchange on the Line with a third-party connecting carrier. SRRR certifies that its projected annual revenues are not expected to exceed $5 million or exceed the level that would qualify it as a Class III rail carrier.

The earliest this transaction may be consummated is November 21, 2021, the effective date of the exemption (30 days after the verified notice was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than November 12, 2021.

All pleadings, referring to Docket No. FD 36546, should be filed with the Surface Transportation Board via e-filing on the Board's website. In addition, a copy of each pleading must be served on SRRR's representative, Thomas W. Wilcox, Law Office of Thomas W. Wilcox, LLC, 1629 K Street NW, Suite 300, Washington, DC 20006.

According to SRRR, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: November 2, 2021.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2021–24282 Filed 11–4–21; 8:45 am]

BILLING CODE 4915–01–P

[1] According to the verified notice, the Line historically has connected to BNSF Railway Company (BNSF) via a switch connection to two BNSF-owned ancillary tracks that run parallel to BNSF's mainline tracks that run by the Site. SRRR states that it will, through a separate agreement, also lease those ancillary tracks from BNSF.

[2] SRRR anticipates that Burlington Junction Railroad (BJRR) will be that third-party railroad.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of rquest to release airport property for land disposal

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of request to rule on release of airport property for land disposal at the Ankeny Regional Airport (IKV), Ankeny, Iowa.

SUMMARY: The FAA proposes to rule and invites public comment on the release of land at the Ankeny Regional Airport (IKV), Ankeny, Iowa, under the provisions of 49 U.S.C. 47107(h)(2).

DATES: Comments must be received on or before December 6, 2021.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Amy J. Walter, Airports Land Specialist, Federal Aviation Administration, Airports Division, ACE–620G, 901 Locust, Room 364, Kansas City, MO 64106.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to: Amy S. Beattie, Brick Gentry PC, Attorney for the Polk County Aviation Authority, 6701 Westown Parkway, Suite 100, West Des Moines, Iowa 50266, (515) 274–1450.

FOR FURTHER INFORMATION CONTACT: Amy J. Walter, Airports Land Specialist, Federal Aviation Administration, Airports Division, ACE–620G, 901 Locust, Room 364, Kansas City, MO 64106, (816) 329–2603, *amy.walter@faa.gov.* The request to release property may be reviewed, by appointment, in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release one tract of land consisting of approximately 16.06 acres of airport property at the Ankeny Regional Airport (IKV) under the provisions of 49 U.S.C. 47107(h)(2). On October 28, 2021, the Attorney for the Polk County Aviation Authority requested a release from the FAA to sell a tract of land, 16.06 acres. Buyer, ATI Capital, LLC, will use the land for development. On November 1, 2021, the FAA determined the request to release property at the Ankeny Regional Airport (IKV) submitted by the Sponsor meets the procedural requirements of the Federal Aviation Administration and the release of the property does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this notice.

The following is a brief overview of the request:

The Ankeny Regional Airport (IKV) is proposing the release of airport property containing 16.06 acres, more or less. The release of land is necessary to comply with Federal Aviation Administration Grant Assurances that do not allow federally acquired airport property to be used for non-aviation purposes. The sale of the subject property will result in the land at the Ankeny Regional Airport (IKV) being changed from aeronautical to non-aeronautical use and release the lands from the conditions of the Airport Improvement Program Grant Agreement Grant Assurances in order to dispose of the land. In accordance with 49 U.S.C. 47107(c)(2)(B)(i) and (iii), the airport will receive fair market value for the property, which will be subsequently reinvested in another eligible airport improvement project for general aviation use.

Any person may inspect, by appointment, the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**. In addition, any person may, upon appointment and request, inspect the application, notice and other documents determined by the FAA to be related to the application in person at the Ankeny City Hall.

Issued in Kansas City, MO, on November 1, 2021.

James A. Johnson,

Director, FAA Central Region, Airports Division.

[FR Doc. 2021–24190 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Waiver of Aeronautical Land Use Assurance: Wellington Municipal Airport (EGT), Wellington, KS

AGENCY: Federal Aviation Administration (FAA), Transportation (DOT).

ACTION: Notice of intent of waiver with respect to land use change from aeronautical to non-aeronautical.

SUMMARY: The Federal Aviation Administration (FAA) is considering a proposal from the City of Wellington, KS, to release a 0.01 acre parcel of land from the federal obligation dedicating it to aeronautical use and to authorize this parcel to be used for revenue-producing, non-aeronautical purposes.

DATES: Comments must be received on or before December 6, 2021.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Amy J. Walter, Airports Land Specialist, Federal Aviation Administration, Airports Division, ACE–620G, 901 Locust, Room 364, Kansas City, MO 64106.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to: Matt Wiebe, Airport Manager, Wellington Municipal Airport, 317 S. Washington, Wellington, KS 67152, (620) 440–2213.

FOR FURTHER INFORMATION CONTACT: Amy J. Walter, Airports Land Specialist, Federal Aviation Administration, Airports Division, ACE–620G, 901 Locust Room 364, Kansas City, MO 64106, Telephone number (816) 329–2603, Fax number (816) 329–2611, email address: *amy.walter@faa.gov.*

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to change a 0.01 acre parcel of airport property at the Wellington Municipal Airport (EGT) from aeronautical use to non-aeronautical for revenue producing use. This parcel will be leased to a GKN Aerospace Precision Machining, a current tenant, to construct a 25 ft. x 25 ft. storm shelter.

No airport landside or airside facilities are presently located on this parcel, nor are airport developments contemplated in the future. There is no current use of the surface of the parcel. The parcel will serve as a revenue producing lot with the proposed change from aeronautical to non-aeronautical. The request submitted by the Sponsor meets the procedural requirements of the Federal Aviation Administration and the change to non-aeronautical status of the property does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this Notice.

The following is a brief overview of the request:

The Wellington Municipal Airport (EGT) is proposing the use release of a 0.01 acre parcel of land from aeronautical to non-aeronautical. The use release of land is necessary to comply with Federal Aviation Administration Grant Assurances that do not allow federally acquired airport property to be used for non-aviation purposes. The rental of the subject property will result in the land at the Wellington Municipal Airport (EGT) being changed from aeronautical to non-aeronautical use and release the lands from the conditions of the Airport Improvement Program Grant Agreement Grant Assurances. In accordance with 49 U.S.C. 47107(c) (2) (B) (i) and (iii), the airport will receive fair market rental value for the property. The annual income from rent payments will generate a long-term, revenue-producing stream that will further the Sponsor's obligation under FAA Grant Assurance number 24, to make the Wellington Municipal Airport as financially self-sufficient as possible.

Any person may inspect, by appointment, the request in person at the FAA office listed above. In addition, any person may upon request, inspect the application, notice and other documents determined by the FAA to be related to the application in person at the Wellington Municipal Airport.

Issued in Kansas City, MO, on October 27, 2021.

James A. Johnson,

Director, FAA Central Region, Airports Division.

[FR Doc. 2021–24195 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. FHWA–2020–0020]

Surface Transportation Project Delivery Program; Arizona Department of Transportation Final FHWA Audit Report

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: The Moving Ahead for Progress in the 21st Century Act (MAP–21) established the Surface Transportation Project Delivery Program that allows a State to assume FHWA's environmental responsibilities for environmental review, consultation, and compliance under the National Environmental Policy Act (NEPA) for Federal highway projects. When a State assumes these Federal responsibilities, the State becomes solely responsible and liable for carrying out the responsibilities it has assumed, in lieu of FHWA. This program mandates annual audits during each of the first four years of State participation to ensure compliance with program requirements. This is the first audit of the Arizona Department of Transportation's (ADOT) performance of its responsibilities under the Surface Transportation Project Delivery Program (NEPA Assignment Program). This notice finalizes the first audit report for ADOT.

FOR FURTHER INFORMATION CONTACT: Mr. Neel Vanikar, Office of Project Development and Environmental Review, (202) 366–2068, *neel.vanikar@dot.gov,* Federal Highway Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, or Mr. Patrick Smith, Office of the Chief Counsel, (202) 366–1345, *patrick.c.smith@dot.gov,* Federal Highway Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 8:00 a.m. to 4:30 p.m., Eastern Standard Time, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this notice may be downloaded from the specific docket page at *www.regulations.gov,* from the Office of the Federal Register's website at *www.FederalRegister.gov,* or from the Government Publishing Office's website at *www.GovInfo.gov.*

Background

The Surface Transportation Project Delivery Program, codified at 23 U.S.C. 327, commonly known as the NEPA Assignment Program, allows a State to assume FHWA's environmental responsibilities for review, consultation, and compliance for Federal highway projects. When a State assumes these Federal responsibilities, the State becomes solely liable for carrying out the responsibilities it has assumed, in lieu of FHWA. The ADOT published its application for NEPA assumption on June 29, 2018, and solicited public

comment. After considering public comments, ADOT submitted its application to FHWA on November 16, 2018. The application served as the basis for developing a Memorandum of Understanding (MOU) that identifies the responsibilities and obligations that ADOT would assume. The FHWA published a notice of the draft MOU in the **Federal Register** on February 11, 2019, at 84 FR 3275, with a 30-day comment period to solicit the views of the public and Federal agencies. After the close of the comment period, FHWA and ADOT considered comments and proceeded to execute the MOU. Effective April 16, 2019, ADOT assumed FHWA's responsibilities under NEPA, and the responsibilities for NEPA-related Federal environmental laws described in the MOU.

Section 327(g) of Title 23, U.S.C., requires the Secretary to conduct annual audits to ensure compliance with the MOU during each of the first four years of State participation and, after the fourth year, monitor compliance. The FHWA must make the results of each audit available for public comment. This notice finalizes the first audit report for ADOT.

Authority: Section 1313 of Public Law 112–141; Section 6005 of Public Law 109–59; 23 U.S.C. 327; 23 CFR part 773.

Stephanie Pollack,

Acting Administrator, Federal Highway Administration.

Surface Transportation Project Delivery Program Final FHWA Audit #1 of the Arizona Department of Transportation

Executive Summary

This is Audit #1 of the Arizona Department of Transportation's (ADOT) assumption of National Environmental Policy Act (NEPA) responsibilities under the Surface Transportation Project Delivery Program. Under the authority of 23 U.S.C. 327, ADOT and the Federal Highway Administration (FHWA) executed a memorandum of understanding (MOU) on April 16, 2019, to memorialize ADOT's NEPA responsibilities and liabilities for Federal-aid highway projects and other related environmental reviews for highway projects in Arizona. This 23 U.S.C. 327 MOU covers environmental review responsibilities for projects that require the preparation of environmental assessments (EA), environmental impact statements (EIS), and non-designated individual categorical exclusions. A separate MOU between FHWA and ADOT, pursuant to 23 U.S.C. 326, authorizes environmental review responsibilities for other categorical exclusions (CE). This audit does not cover the CE responsibilities and projects assigned to ADOT under the 23 U.S.C. 326 MOU.

The FHWA conducted an audit of ADOT's performance according to the terms of the MOU March 9–12, 2020. Prior to the audit, the FHWA audit team held internal meetings to prepare for an on-site visit to the Arizona Division and ADOT offices. Prior to the on-site visit, the audit team reviewed ADOT's environmental manuals and procedures, NEPA project files, ADOT's response to FHWA's pre-audit information request (PAIR), and ADOT's NEPA Assignment Self-Assessment Report. During the March 2020 audit, the audit team conducted interviews with staff from ADOT Environmental Planning (EP) and ADOT's external partners, and prepared preliminary audit results. The audit team presented these preliminary results to ADOT EP leadership on March 12, 2020.

Overall, the audit team found that ADOT has carried out the responsibilities it has assumed consistent with the intent of the MOU and ADOT's application. The ADOT continues to develop, revise, and implement procedures and processes required to deliver its NEPA Assignment Program. This report describes several observations and successful practices. Through this report, FHWA is notifying ADOT of two non-compliance observations that require ADOT to take corrective action. By addressing the observations in this report, ADOT will continue to assure successful program assignment.

Background

The purpose of the audits performed under the authority of 23 U.S.C. 327 is to assess a State's compliance with the provisions of the MOU as well as all applicable Federal statutes, regulations, policies, and guidance. The FHWA's review and oversight obligation entails the need to collect information to evaluate the success of the NEPA Assignment Program; to evaluate a State's progress toward achieving its performance measures as specified in the MOU; and to collect information for the administration of the NEPA Assignment Program. This report summarizes the results of the first audit in Arizona and ADOT's progress towards meeting the program review objectives identified in the MOU. Following this audit, FHWA will conduct three additional annual NEPA Assignment Program audits in Arizona.

Scope and Methodology

The overall scope of this audit review is defined both in statute (23 U.S.C. 327) and the MOU (Part 11). The definition of an audit is one where an independent unbiased body makes an official and careful examination and verification of accounts and records, especially of financial accounts. Auditors who have special training with regard to accounts or financial records may follow a prescribed process or methodology in conducting an audit of those processes or methods. The FHWA considers its review to meet the definition of an audit because it is an unbiased, independent, official, and careful examination and verification of records and information about ADOT's assumption of environmental responsibilities.

The audit team consisted of NEPA subject matter experts (SME) from FHWA Headquarters and Resource Center, as well as staff from FHWA's Arizona Division. This audit is an unbiased official action taken by FHWA, which included an audit team of diverse composition, and followed an established process for developing the review report and publishing it in the **Federal Register**.

The audit team reviewed six NEPA Assignment Program elements: program management; documentation and records management; quality assurance/quality control (QA/QC); performance measures; legal sufficiency; and training. The audit team considered three additional focus areas for this review: project-level conformity procedures; Section 4(f) procedures; and public involvement procedures.

The audit team conducted a careful examination of ADOT policies, guidance, and manuals pertaining to NEPA responsibilities, as well as a representative sample of ADOT's project files. Other documents, such as ADOT's PAIR responses and ADOT's Self-Assessment Report, also informed this review. In addition, the audit team interviewed staff from ADOT EP and ADOT's external partners, both in person and via teleconference.

The timeframe defined for this first audit includes highway project environmental approvals completed between April 16, 2019, and December 31, 2019. During this timeframe, ADOT completed NEPA approvals and documented NEPA decision points for 12 projects. Due to the small sample size, the audit team reviewed all 12 projects. This consisted of four Individual CEs, one EA with a Finding of No Significant Impact (FONSI), two draft EAs, one EA initiated with scoping completed, one draft EIS, and three EA re-evaluations.

The PAIR submitted to ADOT contained 23 questions covering all six NEPA Assignment Program elements.

The audit team developed specific follow-up questions for the on-site interviews with ADOT staff based on ADOT responses to the PAIR.

The audit team conducted a total of 17 interviews. Interview participants included staff from ADOT EP, Arizona Attorney General's Office (AGO), Environmental Protection Agency (EPA) Region 9, Arizona Game and Fish Department (AZGFD), Maricopa Association of Governments (MAG), and the City of Phoenix.

The audit team compared ADOT manuals and procedures to the information obtained during interviews and project file reviews to determine if ADOT's performance of its MOU responsibilities is in accordance with ADOT procedures and Federal requirements. The audit team documented individual observations and successful practices during the interviews and reviews and combined these under the six NEPA Assignment Program elements. The audit results are described below by program element.

Overall Audit Opinion

The audit team found ADOT has carried out the responsibilities it has assumed consistent with the intent of the MOU and ADOT's application. The FHWA is notifying ADOT of two non-compliance observations that require ADOT to take corrective action. By addressing the observations cited in this report, ADOT will continue to assure a successful program.

Successful Practices and Observations

Successful practices are practices that the team believes are positive, and encourages ADOT to consider continuing or expanding those programs in the future. The audit team identified numerous successful practices in this report.

Observations are items the audit team would like to draw ADOT's attention to, which may improve processes, procedures, and/or outcomes. The team identified three observations in this report.

Non-compliance observations are instances where the audit team finds the State is not in compliance or is deficient with regard to a Federal regulation, statute, guidance, policy, State procedure, or the MOU. Non-compliance may also include instances where the State has failed to secure or maintain adequate personnel and/or financial resources to carry out the responsibilities they have assumed. The FHWA expects the State to develop and implement corrective actions to address all non-compliance observations. The audit team identified two non-compliance observations in this report.

The audit team shared initial results during the site visit closeout and shared the draft audit report with ADOT to provide them the opportunity to clarify any observation, as needed, and/or begin implementing corrective actions to improve the program. The FHWA will consider actions taken by ADOT to address these observations as part of the scope of the second audit.

Successful Practices and Observations

Program Management

Successful Practices

The ADOT EP has developed several detailed guidance manuals for implementing NEPA Assignment and evaluating environmental resources. These manuals are readily available online at ADOT's environmental website. The ADOT continuously updates their manuals and has a process for tracking updates by including a list of changes as an appendix in each version. Several staff members stated they regularly consult the guidance manuals and are informed of updates.

The ADOT EP has developed internal procedures for resolving and escalating conflicts. The ADOT Project Development Procedures Manual describes these escalation procedures. The ADOT has found this to be an effective tool to assist in evaluating controversial issues, identifying appropriate levels of communication, and determining the best approach for dispute resolution.

During interviews with staff, the audit team learned that ADOT EP makes a considerable effort at internal communication and coordination through meetings, emails, and informal interaction. The staff holds weekly and monthly meetings for environmental planners and technical groups to discuss project issues, address program-level questions, and update staff on guidance. Interviewed staff said they were well-informed about procedures and comfortable discussing complex situations with team leads and technical experts. In addition, ADOT EP attends partnering/preconstruction meetings with other ADOT sections to convey environmental commitments and to stay informed of project changes.

During interviews, EPA, AZGFD, and the City of Phoenix commented on ADOT EP's collaboration and communication efforts with them. The EPA was appreciative of ADOT EP holding bi-monthly coordination meetings to discuss the status of projects and commented on their much-improved relationship with ADOT. The AZGFD acknowledged and appreciated the opportunities to provide input through the outreach efforts of ADOT biologists on projects with wildlife concerns. The City of Phoenix noted ADOT's improved communication with local governments and efforts to increase flexibility in the environmental review process. The audit team recognizes ADOT EP's outreach efforts with these external partners. One area identified by the audit team in need of improved collaboration is project-level conformity determinations, where legal responsibility remains assigned to FHWA.

Observations

Non-Compliance Observation #1: Incomplete Project Files Submission

For this audit, pursuant to MOU Sections 8.2.2 and 8.2.3, FHWA requested all project files pertaining to the NEPA approvals and documented NEPA decision points completed during the audit review period. The request specified the approved NEPA document and all supporting documentation related to the decision milestones, such as consultation letters, technical memos, and resource evaluations (email to ADOT November 26, 2019). The FHWA provided additional clarification to ADOT regarding the types of NEPA approvals and NEPA decision documents that ADOT should submit (email to ADOT December 18, 2019).

The audit team found several inconsistences between ADOT's procedures for maintaining project files (as identified in the ADOT CE Checklist Manual, ADOT EA/EIS Manual, ADOT QA/QC Plan, and ADOT Project Development Procedures Manual) and the project file documentation provided to FHWA. The ADOT's procedures specify utilizing a standard folder structure for all projects and saving all project documentation and supporting information in the project files. However, the project files submitted by ADOT for this audit were incomplete and did not include all supporting documentation. The project files that ADOT submitted consisted primarily of final decision documents and, in most cases, did not include correspondence, internal communication, technical memos/reports, or other types of information to support NEPA decisions or demonstrate how ADOT evaluated resources.

The audit team learned during interviews that ADOT EP management created a duplicate project file for each project which consisted of a subset of their project files. Due to the incomplete project files, it is unclear how ADOT is

maintaining electronic project files and administrative records, and how ADOT is complying with its procedures and the terms of the 23 U.S.C. 327 MOU as they apply to records retention. The audit team determined that ADOT EP management made the decision to not submit all requested project files for review by FHWA as required by the MOU (Section 8.2.3). In the last 23 U.S.C. 326 MOU monitoring review, FHWA observed this same practice and informed ADOT that such a practice was in non-compliance with the MOU. Just as that practice was in non-compliance with the 23 U.S.C. 326 MOU, this practice is also in non-compliance with the 23 U.S.C. 327 MOU.

Observation #1: Use of the Federal Infrastructure Permitting Dashboard

The ADOT is responsible for inputting project information for assigned projects into the Federal Infrastructure Permitting Dashboard, per MOU Section 8.5.1. During the audit, the audit team reviewed the Permitting Dashboard and found that it did not include information for any of the applicable projects assigned to ADOT. The audit team confirmed during interviews that ADOT has not updated the dashboard. The audit team acknowledges that ADOT is working with FHWA to obtain access to the dashboard and address this issue.

Documentation and Records Management

The audit team reviewed 12 projects as part of this audit. This consisted of four Individual CEs, one EA with a FONSI, two draft EAs, one EA initiated with scoping completed, one draft EIS, and three EA re-evaluations.

Successful Practices

The ADOT EP has developed several standard templates (*e.g.,* checklists, forms, etc.) to document various actions and decision-points throughout the NEPA process. These are an effective tool for ADOT to consistently evaluate environmental resources and document decisions. Staff indicated that these templates have aided in streamlining the review process and provided consistency across projects.

Observations

Non-Compliance Observation #2: Project-Level Conformity Compliance Issues

The statutory provisions of the NEPA Assignment Program, along with Section 3.2.1 of the MOU, prohibit ADOT from assuming the responsibility for making conformity determinations for projects processed under the 23 U.S.C. 327 MOU. However, pursuant to the Federal transportation conformity regulations at 40 CFR 93.105(c) and Section 7.2.1 of the MOU, ADOT and FHWA Arizona Division can agree on procedures that allow ADOT to engage in activities to assist in this process and establish when and how consultation with FHWA must occur.

The audit team reviewed ADOT's protocols for seeking FHWA's project-level conformity determinations, conducted a focused review of project-level conformity procedures on six projects, and interviewed ADOT, MAG, and EPA staff. The audit team found that ADOT had not given FHWA a chance to review and agree on the protocols and, as a result, the protocols do not provide for the appropriate consultation, coordination, and communication with FHWA and other agencies, such as EPA and MAG, to ensure the projects meet the project-level conformity requirements where required.

The audit team found documentation for two projects showing that ADOT staff did not coordinate with FHWA on the application of conformity requirements and, by doing so, ADOT took actions that were not assigned to them. This failure to coordinate prevented FHWA from meeting its conformity determination responsibilities. The ADOT incorrectly concluded that the conformity requirements did not apply to one of the two projects because they assumed that the project would not trigger any FHWA approvals. The ADOT proceeded to complete NEPA without FHWA's conformity determination. This deficient approval prevents FHWA from authorizing the project until the conformity requirements are met. In another project, ADOT incorrectly determined that a widening project was exempt from project conformity under 40 CFR 93.126.

The audit team found multiple projects that did not demonstrate ADOT's compliance with interagency consultation requirements, per 40 CFR 93.105. The ADOT appears to have conducted some degree of interagency consultation but information on such consultation was not included in the project files. Therefore, it is unclear whether the interagency consultation agencies had an opportunity to participate in consultation or if ADOT provided them an opportunity to review and comment on the materials as required by 40 CFR 93.105 and MOU Section 7.2.1. During interviews, EPA expressed concerns regarding how ADOT conducts project-level interagency consultation. Both EPA and MAG also felt that the interagency consultation is not fully transparent since ADOT does not: (1) Share comments with all interagency consultation agencies throughout the process; (2) provide responses to agency comments; and (3) consistently follow up with agencies to ensure their comments are adequately addressed. In cases where a project-level conformity determination is required, the interagency consultation process must meet the conformity rule requirements found in 40 CFR 93.105.

During interviews, ADOT staff did not demonstrate a full of understanding project-level conformity requirements. The audit team identified that ADOT staff were not aware that: (1) Certain FHWA approvals (in addition to Federal funding) may necessitate a project-level conformity determination; (2) certain situations may require a redetermination of project-level conformity under 40 CFR 93.104(d); (3) the importance of specific traffic data requirements for the reviews; and (4) the public involvement requirements associated with project-level conformity.

The lack of agreed-upon interagency consultation procedures with clear roles, responsibilities, and coordination protocols, particularly between ADOT and FHWA, creates a significant risk of project schedule delays and, ultimately, project non-compliance. The ADOT should revise their procedures to be consistent with 40 CFR 93.105 and obtain agreement from FHWA to make sure the correct workflows are established, the responsibilities of FHWA are not curtailed, and that interagency consultation is transparent. Until agreed-upon protocols between FHWA and ADOT are in place, ADOT should consult with FHWA on all projects in non-attainment and maintenance areas to determine if conformity determination will be required for the project and the appropriate interagency consultation needed.

Observation #2: Inconsistencies and Deficiencies Based on the Review of Project File Documentation

The audit team preliminarily identified several inconsistencies between ADOT's procedures for documenting project decisions (as identified in the ADOT CE Checklist Manual, ADOT EA/EIS Manual, ADOT QA/QC Plan, and ADOT Project Development Procedures Manual) and the incomplete project file documentation provided. Section 4.2.4 of the MOU specifies that ADOT must

implement documentation procedures to support appropriate environmental analysis and decision-making under NEPA and associated laws and regulations. The FHWA informed ADOT EP leadership during the audit week that project files were incomplete and, in response, ADOT submitted additional project files and supporting documentation. The ADOT was provided a second opportunity after the audit week to clarify inconsistences identified by the audit team and answer follow-up questions regarding the project documentation.

After completing the project file review (including the supplemental information provided by ADOT), the audit team identified the following procedural deficiencies relating to the MOU and FHWA's regulations, policies, and guidance:

- One project did not include the disclosure statement on the DEIS cover page regarding the intent to combine the final EIS and record of decision (ROD) as identified in the January 14, 2013, interim guidance memorandum on MAP–21 Section 1319 Accelerated Decision making in Environmental Reviews.
- One corridor widening project did not demonstrate independent utility and logical termini as required in 23 CFR 771.111(f)(1) and 23 CFR 771.111(f)(2).
- One project did not demonstrate that funding for the project is programmed beyond Fiscal Year 2019 and did not demonstrate that the project is identified on a current Statewide Transportation Improvement Program (STIP) per 23 CFR 771.113(a)(3).

In addition, the audit team found several inconsistencies between ADOT's documentation of Section 4(f) determinations (as identified in ADOT's Section 4(f) procedures and FHWA Section 4(f) regulation and guidance) and the project file documentation. Due to the inadequate information provided, it is unclear how ADOT is implementing Section 4(f) and how ADOT is complying with its Section 4(f) procedures. The audit team identified the following inconsistencies in project files relating to Section 4(f) evaluations and determinations:

- One project included a Section 106 no adverse effect finding and Section 4(f) no use determinations for six historic properties; however, ADOT did not provide any information demonstrating how they evaluated these resources under Section 4(f), or if they consulted the officials with jurisdiction over the resources.
- Two projects included a Section 106 finding of either adverse effect or no adverse effect, indicating the presence of potential Section 4(f) resources; however, ADOT did not provide any information demonstrating how they evaluated these resources under Section 4(f), or if they had consulted the officials with jurisdiction over the resources.
- One project included a Section 4(f) joint development determination but it is unclear what information ADOT used to support this determination (such as a master plan map or other planning information), or if they consulted the official with jurisdiction over the resource regarding potential impacts to the Section 4(f) resource.
- One project included a temporary occupancy determination and the description of the impact to the resource is inconsistent with the definition provided in 23 CFR 774.13(d)(3).
- One project stated that a Section 4(f) resource within the project area is jointly owned by two entities, but it is unclear if ADOT consulted with both officials with jurisdiction regarding the *de minimis* use since only one official with jurisdiction concurred with the *de minimis* use.

The audit team acknowledges that ADOT is aware that implementation of Section 4(f) is an area in need of improvement and recognizes their efforts to update its procedures, including ADOT recently developing standard evaluation forms.

Quality Assurance/Quality Control (QA/QC)

The audit team verified that ADOT has procedures in place for QA/QC which are described in the ADOT QA/QC Manual and ADOT Project Development Procedures Manual. The ADOT has developed QC checklists and forms to assist in implementing project-level QC procedures. During the project file reviews, the audit team noted some variation in how ADOT implements project-level QC procedures, and inconsistencies in how ADOT documents QC reviews. It was unclear how ADOT conducts thorough project-level QC reviews (completeness vs. accuracy), how ADOT corrects errors it identifies during QC reviews, and how the environmental planners coordinate with technical experts during QC reviews. Staff indicated during interviews that informal QC reviews are often conducted before QC checklists are completed, though it is unclear how this process is tracked to ensure comments are addressed. Due to these inconsistencies, the audit team was unable to fully assess the implementation of project-level QC procedures. The FHWA will continue to evaluate this program objective in subsequent audits.

Performance Measures

Observations

Observation #3: Incomplete Development and Implementation of Performance Measures

The audit team reviewed ADOT's development and implementation of performance measures to evaluate their program as required in the MOU (Part 10.2.1). The ADOT's QA/QC Plan and self-assessment report identified several performance measures but both indicated that ADOT was still refining these measures and had not fully implemented them. The ADOT's PAIR response stated that ADOT has focused on tracking projects for schedule issues and has not begun gathering data for other performance measures. The self-assessment report did not include reporting data for any of the performance measures. The audit team confirmed during staff interviews that ADOT does not have data for its performance measures and is looking to further refine its performance measures. Due to the lack of performance measure data, the audit team determined that ADOT has not fully established and initiated data collection as it relates to performance metrics per the MOU.

Legal Sufficiency

Through information provided by ADOT and an interview by the FHWA Office of Chief Counsel with an Assistant Attorney General (AAG) assigned to ADOT's NEPA Assignment program, the auditors determined ADOT had not conducted formal legal sufficiency reviews of assigned environmental documents during the audit period. Currently, ADOT retains the services of two AAGs for NEPA Assignment reviews and related matters. The assigned AAGs have received formal and informal training in environmental law matters. The ADOT also has the ability to retain outside counsel to review projects or conduct litigation should the need arise.

Successful Practice

Through the interview, the audit team learned ADOT seeks to involve lawyers early in the environmental review phase, with AAGs participating in project coordination team meetings and reviews of early drafts of environmental documents. In addition, ADOT and the AGO have a process in place by which ADOT can request written legal opinions and advice from an AAG on environmental review legal matters. For formal reviews, the process would

include a formal transmittal memo from an ADOT environmental manager, a review package (hard copy or electronic), and a completed ADOT EA/EIS Quality Control Checklist.

Training

The audit team reviewed ADOT's 2020 Training Plan and ADOT's PAIR responses pertaining to its training program. The ADOT's training program includes in-house, web-based, and instructor-led courses training opportunities for staff. Since assuming NEPA responsibilities, ADOT has held several formal training courses and plans to continue these efforts during the upcoming year. The ADOT provides new hires with structured onboarding training which includes coaching, mentoring, and collaborative on-the-job training to facilitate professional development. The ADOT EP Training Officer tracks staff training needs and completion of courses and updates this document quarterly. Staff remarked during interviews on the availability of training offered to them and opportunities to travel out of State for specialty technical courses.

Successful Practices

The audit team commends ADOT for developing a detailed training plan and committing resources to provide training opportunities for staff. The ADOT EP encourages staff to pursue individual training interests and has undertaken efforts to ensure staff maintains professional certifications. The ADOT EP has developed a web-based training course for staff as an introduction to NEPA Assignment. To further support the training program, ADOT EP utilizes a dedicated training coordinator within the environmental section.

Finalizing This Report

The FHWA published a draft version of this report in the **Federal Register** on December 28, 2020 (85 FR 84454), and made it available for public review and comment for 30 days in accordance with 23 U.S.C. 327(g). The FHWA received two responses to the **Federal Register** notice during the public comment period for the draft report. One comment was submitted by ADOT. The nature of ADOT's comment was substantially the same as those provided by ADOT during their preliminary review of the draft report which were considered in developing the draft report. The FHWA considered this additional comment from ADOT and determined no changes were needed to the content of the report since the comment had been previously considered in the draft report. The final version of the audit report reflects consideration of all of ADOT's comments. The second comment from the American Road and Transportation Builders Association expressed their support of the program and did not require any changes to the content of the report. This is FHWA's final version of the audit report.

The FHWA acknowledges that ADOT has begun to address some of the observations identified in this report and recognizes ADOT's efforts toward improving their program. The FHWA will consider the results of this audit in preparing the scope of the next annual audit. The next audit report will include a summary that describes the status of ADOT's corrective and other actions taken in response to this audit's conclusions.

[FR Doc. 2021–24215 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2006–26367]

Meetings: Motor Carrier Safety Advisory Committee (MCSAC); Notice of Public Meeting

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation.

ACTION: Notice of public meeting.

SUMMARY: FMCSA announces a meeting of MCSAC, which will take place via videoconference.

DATES: The meeting will be held Monday and Tuesday, December 6 and 7, 2021, from 9:15 a.m. to 4:30 p.m., Eastern Time. Requests for accommodations because of a disability must be received by Monday, November 29. Requests to register and/or to submit written materials to be reviewed during the meeting must be received no later than Monday, November 29.

ADDRESSES: The meeting will be held via videoconference. Those members of the public who would like to participate should go to *https://www.fmcsa.dot.gov/advisory-committees/mcsac/meetings* to access the meeting, task statements, a detailed agenda for the entire meeting, meeting minutes and additional information on MCSAC and its activities. The meeting will be recorded, and a link to the recording will be posted on the FMCSA website.

FOR FURTHER INFORMATION CONTACT: Ms. Shannon L. Watson, Senior Advisor to the Associate Administrator for Policy, Federal Motor Carrier Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, (202) 360–2925, *mcsac@dot.gov.* Any MSCAC-related request or submission should be sent via email to the person listed in this section.

Information may also be submitted by docket through Docket Number FMCSA–2006–26367 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590.
- *Hand Delivery:* Docket Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC, between 9 a.m. and 5 p.m., E.T. Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Docket Operations.

SUPPLEMENTARY INFORMATION:

I. Background

Purpose of the Committee

MCSAC was established to provide FMCSA with advice and recommendations on motor carrier safety programs and motor carrier safety regulations. MCSAC is composed of up to 25 voting representatives from the motor carrier safety advocacy, safety enforcement, labor, and industry sectors. The diversity of MCSAC ensures the requisite range of views and expertise necessary to discharge its responsibilities. MCSAC operates as a discretionary committee under the authority of the U.S. Department of Transportation (DOT), established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. app. 2).

Meeting Agenda

MCSAC will resume consideration of Task 21–1, relating to supply chains for the transportation industrial base. Task 21–1 includes discussions about workforce skills for the motor carrier sector and identified gaps, opportunities, and potential best practices in meeting the future workforce needs and driver retention for the motor carrier industry. The task also includes discussions about the role of transportation systems in supporting existing supply chains and risks

associated with those transportation systems and the safe and efficient transportation of passengers and freight across our Nation. Subsequent to its July meeting, MCSAC engaged its Driver Subcommittee for its consideration of workforce needs, the results of which are to be submitted to MCSAC for its consideration and final recommendations to FMCSA.

Additionally, MCSAC will resume consideration of Task 20–1, which relates to changes to the package and small goods delivery sector. A number of companies are now using small vehicles (*e.g.,* vehicles with a gross vehicle weight rating less than 10,000 pounds) to deliver goods, and there appears to be a gap in safety oversight of both drivers and vehicles. For this task, members will hear from FMCSA experts on trends in the Fatality Analysis Reporting System (FARS) and Motor Carrier Management Information System (MCMIS) crash and highway safety data.

II. Meeting Participation

Advance registration is requested. Please register at *www.fmcsa.dot.gov/mcsac* by the deadline referenced in the **DATES** section. The meeting will be open to the public for its entirety. The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Oral comments from the public will be heard throughout the meeting, at the discretion of the MCSAC chairman and designated federal officer. FMCSA asks that individuals from the public limit their comments to one minute on the issues under consideration only. Members of the public may submit written comments to the person listed in the **FOR FURTHER INFORMATION CONTACT** section on the topics to be considered during the meeting by the deadline referenced in the **DATES** section.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2021–24245 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Early Scoping Notice for the Central Puget Sound Regional Transit Authority Proposed Everett Link Extension (EVLE) From Lynnwood to Everett, WA

AGENCY: Federal Transit Administration, Department of Transportation (DOT).

ACTION: Early scoping notice.

SUMMARY: The Federal Transit Administration (FTA) and the Central Puget Sound Regional Transit Authority (Sound Transit) issue this early scoping notice to advise tribes, agencies, and the public that FTA and Sound Transit will explore potential route and station alternatives for the Everett Link light rail extension (EVLE or Project) and are starting to determine the scope of the environmental issues associated with the Project. The Project would extend Link light rail from the Lynnwood City Center Station to the Everett Station area in Snohomish County, Washington, and improve connections to the regional transit system and major activity centers. Potential alternatives for a light rail operations and maintenance facility (OMF North) in Snohomish County will also be explored to support the regional Link light rail program, including EVLE.

DATES: Two online public early scoping meetings will be held at the following times (all times are Pacific Standard Time):

- Wednesday, November 17, 2021, from 12:00–1:30 p.m.
- Thursday, November 18, 2021, from 6:00–7:30 p.m.

These early scoping meetings will be conducted in a webinar format, accessible via the internet and by teleconference. Registration for an online public early scoping meeting can be done in advance of the meeting at *everettlink.participate.online.*

FTA and Sound Transit have also scheduled an interagency and tribal early scoping meeting on November 8, 2021, to receive comments from tribes and agencies who have an interest in the proposed Project. Invitations to the tribal and agency early scoping meeting will be sent to appropriate federal, tribal, state, and local government units and will include details on how to participate in the online meeting.

Supplemental information about the Project is provided in the following sections. Sound Transit will also provide information on the alternatives analysis at the early scoping meetings, along with opportunities for comments. Information is also available on the Sound Transit website at *https://www.soundtransit.org/system-expansion/everett-link-extension.*

Written early scoping comments are requested by December 10, 2021, and can be mailed or emailed to the addresses below. Comments can also be provided via the online comment form available at the website address below or left as a voicemail at the phone number below.

ADDRESSES: Kathy Fendt, Sound Transit, 401 S Jackson Street, Seattle, WA 98104–2826, Email: *EverettLinkComments@soundtransit.org,* Project website: *everettlink.participate.online,* Voicemail Phone Number: 888–512–8599. Information in alternative formats: 800–201–4900/TTY: 711 or *accessibility@soundtransit.org.*

FOR FURTHER INFORMATION CONTACT: Mark Assam, Environmental Protection Specialist, Region 10, Federal Transit Administration, 915 Second Avenue, Suite 3142, Seattle WA 98174, phone: 206–220–4465, email: *Mark.Assam@dot.gov.*

SUPPLEMENTARY INFORMATION:

Early Scoping

Early scoping is an optional element of the NEPA process that is intended to invite public, agency, and tribal comments at the earliest reasonable time in project planning, as in the case for this Project, where alignment and siting variations are under consideration in a broadly defined study area. FTA is the lead federal agency under NEPA. Early scoping is also being conducted under the Washington State Environmental Policy Act (SEPA) rules regarding expanded scoping (Washington Administrative Code 197–11–410). Sound Transit is the lead agency under SEPA.

Early scoping can ensure that tribes, agencies, and the public have the opportunity to review and provide comments on the proposal that can then be used to inform subsequent steps in the NEPA process.

Early scoping is being initiated for EVLE during the Project's alternatives development phase. This early scoping notice invites the public and other interested parties to comment on the scope of the alternatives development analysis, including the following: (a) The purpose and need for the Project; (b) the range of alternatives for light rail route, station, and OMF locations; (c) the impacts and benefits to the social, built, and natural environments; and (d) other considerations that are relevant to the evaluation of alternatives. These early scoping efforts are being

conducted in support of NEPA requirements and in accordance with the Council on Environmental Quality's regulations for implementing NEPA.

Purpose and Need for the Project

The purpose of the EVLE is to expand the Link light rail system from the Lynnwood City Center Station to the Everett Station area and provide an operations and maintenance facility in order to:

- Provide high quality, rapid, reliable, accessible, and efficient light rail transit service to communities in the Project corridor as defined through the local planning process and reflected in the Sound Transit 3 (ST3) Plan (Sound Transit 2016).
- Improve regional mobility by increasing connectivity and capacity in the EVLE corridor from the Lynnwood Transit Center to the Everett Station area to meet projected transit demand.
- Connect regional centers as described in adopted regional and local land use, transportation, and economic development plans and Sound Transit's *Regional Transit Long-Range Plan* (Sound Transit 2014).
- Implement a system that is technically and financially feasible to build, operate, and maintain.
- Expand mobility for the corridor and region's residents, including explicit consideration for transit-dependent, low-income, and minority populations.
- Encourage equitable and sustainable growth in station areas through support of transit-oriented development and multimodal integration in a manner that is consistent with local land use plans and policies, including South Transit's *Equitable Transit Oriented Development Policy* (Sound Transit 2018) and *Sustainability Plan* (Sound Transit 2019).
- Encourage convenient, safe, and equitable nonmotorized access to stations, such as bicycle and pedestrian connections, consistent with Sound Transit's *System Access Policy* (Sound Transit 2013) and *Equity and Inclusion Policy* (Sound Transit 2019).
- Preserve and promote a healthy environment and economy by minimizing adverse impacts on the natural, built, and social environments through sustainable and equitable practices.
- Provide an OMF with the capacity to receive, test, commission, store, maintain, and deploy vehicles to support the intended level of service for system-wide light rail system expansion.
- Develop an OMF that supports efficient and reliable light rail service and minimizes system operating costs.

The Project is needed because:

- Chronic roadway congestion on Interstate 5 (I–5) and State Route (SR) 99—two primary highways connecting communities along the corridor—delays today's travelers, including those using transit, and degrades the reliability of bus service traversing the corridor, particularly during commute periods.
- These chronic, degraded conditions are expected to continue to worsen as the region's population and employment grow.
- Puget Sound Regional Council (the regional metropolitan planning organization) and local plans call for high-capacity transit in the corridor consistent with *VISION 2050* (Puget Sound Regional Council 2020) and the *Regional Transit Long-Range Plan* (Sound Transit 2014).
- Snohomish County residents and communities, including transit-dependent residents and low-income or minority populations, need long-term regional mobility and multimodal connectivity, as called for in the Washington State Growth Management Act (Revised Code of Washington 36.70A.108).
- Regional and local plans call for increased residential and/or employment density at and around high-capacity stations and increased options for multimodal access.
- Environmental and sustainability goals of the state and region, as established in Washington state law and embodied in Puget Sound Regional Council's *VISION 2050* (Puget Sound Regional Council 2020) and *Regional Transportation Plan* (Puget Sound Regional Council 2018), include reducing greenhouse gas emissions by prioritizing transportation investments that decrease vehicle miles traveled.
- The current regional system lacks an OMF with sufficient capacity and suitable location to support the efficient and reliable long-term operations for system-wide light rail expansion, including the next phase of light rail expansion in Snohomish and King counties.
- New light rail maintenance and storage capacity needs to be available with sufficient time to accept delivery of and commission new vehicles to meet fleet expansion needs and to store existing vehicles while the new vehicles are tested and prepared.

Project Description

The Everett Link extension corridor is approximately 16 miles long and extends Link light rail service north from the Lynnwood City Center Station to the Everett Station area. The Project includes six new Link stations and study of one additional provisional station during the planning process. The new light rail stations would be located in the following areas: (a) West Alderwood; (b) Ash Way; (c) Mariner Station; (d) Southwest Everett Industrial Center; (e) State Route (SR) 526/Evergreen; and (f) Everett. The provisional station is in the SR 99/Airport Road area. From Lynnwood, the proposed Link route parallels I–5 to the Mariner Station area, and then travels westward along Airport Road to the SW Everett Industrial Center and eastward along SR 526/Evergreen Way, before it continues northward along I–5 to Everett. The Project also includes a new operations and maintenance facility that will support the system-wide Link light rail system (OMF North), to be located along the alignment in Snohomish County.

Project Context and History

Sound Move, the first phase of regional transit investments, was approved and funded by voters in 1996. Regional transit implemented as part of the Sound Move Plan included various Sounder commuter rail, regional Sound Transit Express bus, and Link light rail services that are now operational, including the Central Link light rail system, and the light rail extension to the University of Washington. In 2008, voters authorized funding for additional regional transit services as part of the Sound Transit 2 (ST2) Plan. The ST2 Plan extends Link light rail by approximately 36 miles including extensions east to Bellevue, south to Federal Way, and north to Northgate and Lynnwood. The Northgate extension opened in October 2021, and the other projects are currently under construction with the Lynnwood Link Extension opening for revenue service in 2024. The third phase of regional transit investments, ST3, was approved and funded by voters in 2016. ST3 will further extend the Link light rail system east from Bellevue to Redmond, south from Federal Way to Tacoma, north from Lynnwood to Everett, and from downtown Seattle to West Seattle and Ballard.

Based on current revenue projections and cost estimates for the Everett Link extension, Sound Transit anticipates opening service from Lynnwood to SW Everett Industrial Center in 2037 and from SW Everett Industrial Center to Everett Station in 2041. The OMF North is currently planned for completion in 2034, and parking at Mariner and

Everett stations is planned for completion in 2046.

Potential Alternatives

Previous planning work done to support development of the ST3 Plan included an examination of a range of potential high-capacity transit modes and alignment options between Lynnwood and Everett, including both bus rapid transit and light rail options on several potential alignments including I–5, SR 99, SR 525 and SR 526. Based on the analysis, a representative project was developed for the Everett Link extension for the purposes of establishing project scope, cost estimates, and ridership forecasts. The representative project developed for all ST3 projects, including the Everett Link extension, formed the basis of the ST3 Plan, financing for which was approved by the voters in 2016. The ST3 representative project is being used to establish the transit mode, corridor, number of stations, and general station locations during alternatives development. It is also the starting point for investigating other reasonable alternatives consistent with the ST3 Plan.

As part of the alternatives development phase for the Project, FTA and Sound Transit will explore alternative alignment, station, and OMF North locations and design configurations that could meet the Project's purpose and need. During this early scoping comment period, FTA and Sound Transit invite comments on the Project purpose and need, the ST3 representative project, other potential alternatives, and environmental issues of concern. Alternatives could include alignments on the west or east side of I–5, or other alternatives that arise during the early scoping comment period. During the alternatives development phase, FTA and Sound Transit will evaluate the relative performance of alternatives using performance measures that reflect the purpose and need for the Project. Examples of these measures include projected light rail ridership; capital, operations and maintenance costs; and potential benefits or burdens to vulnerable populations in the corridor. As part of early scoping, FTA and Sound Transit also invite tribes, agencies, and the public to comment on the types of impacts or benefits that should be considered during the alternatives development phase.

Next Steps

Following early scoping, FTA and Sound Transit anticipate narrowing the range of alternatives for further evaluation in a combined NEPA/SEPA environmental document. If the resulting range of alternatives involves the potential for significant environmental impacts requiring an environmental impact statement (EIS), FTA will publish a Notice of Intent to Prepare an EIS in the **Federal Register**, and Sound Transit will publish a Determination of Significance/Scoping Notice. Tribes, agencies, and the public will be invited to comment on the scope of the EIS at that time.

Authority: 49 CFR 622.101, 23 CFR 771.111, and 40 CFR 1501.7.

Linda M. Gehrke,

Regional Administrator.

[FR Doc. 2021–24181 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0257]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: FREEDOM (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, Transportation (DOT).

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 6, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0257 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2021–0257 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0257, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel FREEDOM is:

—*Intended Commercial Use of Vessel:* ''Owner intends bay and near-shore sunset cruises, events, and parties.''

—*Geographic Region Including Base of Operations:* ''California.'' (Base of Operations: San Diego, CA)

—*Vessel Length and Type:* 42.0′ Motor

The complete application is available for review identified in the DOT docket as MARAD 2021–0257 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2021–0257 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–24197 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0254]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: ST. MARYS PILOT (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, Transportation (DOT).

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 6, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0254 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2021–0254 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0254, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel ST. MARYS PILOT is:

—*Intended Commercial Use of Vessel:* ''To carry United States registered pilots from shore to ship so they may provide pilotage services to foreign vessels on the Great Lakes of Michigan.''

—*Geographic Region Including Base of Operations:* ''Michigan'' (Base of Operations: Brimley, MI)

—*Vessel Length and Type:* 36.9′ Motor

The complete application is available for review identified in the DOT docket as MARAD 2021–0254 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2021–0254 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–24193 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0261]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: DAYS LIKE THIS (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, Transportation (DOT).

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 6, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0261 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2021–0261 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0261, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel DAYS LIKE THIS is:

—*Intended Commercial Use of Vessel:* ''Private yacht charters accommodating passengers on trips around Florida and The Bahamas.''

—*Geographic Region Including Base of Operations:* ''Florida.'' (Base of Operations: Ft. Lauderdale, FL).

—*Vessel Length and Type:* 70.0′ Motor

The complete application is available for review identified in the DOT docket as MARAD 2021–0261 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2021–0261 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

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By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–24201 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0259]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: EXCELSIOR (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, Transportation (DOT).

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 6, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0259 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2021–0259 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0259, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel EXCELSIOR is:

—*Intended Commercial Use of Vessel:* ''This vessel will be available for sailing trips primarily in Florida when not being used by the <owner's name> family.''

—*Geographic Region Including Base of Operations:* ''Florida, Georgia, South Carolina, North Carolina, Virginia, Maryland, Maine, Connecticut, New Hampshire, Louisiana, Texas, Mississippi, Alabama.'' (Base of Operations: Ft. Lauderdale, FL).

—*Vessel Length and Type:* 58.0′ Sail (Catamaran)

The complete application is available for review identified in the DOT docket as MARAD 2021–0259 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the

commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2021–0259 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

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By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary,Maritime Administration.

[FR Doc. 2021–24199 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0255]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: ALLY CAT (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, Transportation (DOT).

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 6, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0255 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2021–0255 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0255, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel ALLY CAT is:

—*Intended Commercial Use of Vessel:* ''Recreation sailing charters and ASA sailing lessons.''

—*Geographic Region Including Base of Operations:* ''California, Oregon, Washington, Hawaii.'' (Base of Operations: San Diego, CA)

—*Vessel Length and Type:* 42.6′ Sail (Catamaran)

The complete application is available for review identified in the DOT docket as MARAD 2021–0255 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application,

and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2021–0255 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

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By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–24194 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0258]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: CHIMERA (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, Transportation (DOT).

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 6, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0258 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2021–0258 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0258, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel CHIMERA is:

—*Intended Commercial Use of Vessel:* ''Passenger only day and overnight charter trips including inland, nearshore and offshore sailing.''
—*Geographic Region Including Base of Operations:* ''Maryland, Virginia, North Carolina, South Carolina, Georgia, Florida.'' (Base of Operations: Charleston, SC)
—*Vessel Length and Type:* 45.0′ Sail (Catamaran)

The complete application is available for review identified in the DOT docket as MARAD 2021–0258 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the

commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2021–0258 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–24198 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0253]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: OCEAN SPIRIT II (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, Transportation (DOT).

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 6, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0253 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2021–0253 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0253, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel OCEAN SPIRIT II is:

—*Intended Commercial Use of Vesssel:* ''Will be used to carry up to a maximum of 12 passengers who are engaged in safe boating education and instruction as well as sightseeing throughout the ports she serves.''

—*Geographic Region Including Base of Operations:* ''California'' (Base of Operations: San Diego, CA)

—*Vessel Length and Type:* 38.4′ Sail (Catamaran)

The complete application is available for review identified in the DOT docket as MARAD 2021–0253 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments

should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2021–0253 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–24192 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0256]

Coastwise Endorsement Eligibility Determination for a Foreign-built Vessel: LORAX (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, Transportation (DOT).

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 6, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0256 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2021–0256 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0256, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel LORAX is:

—*Intended Commercial Use of Vessel:* ''Recreational charters.''

—*Geographic Region Including Base of Operations:* ''Florida, Georgia, South Carolina, North Carolina, Virginia, Maryland, New Jersey, New York, Rhode Island, Connecticut, Maine, New Hampshire.'' (Base of Operations: Palm Beach, FL)

—*Vessel Length and Type:* 82.6′ Motor

The complete application is available for review identified in the DOT docket as MARAD–2021–0256 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the

commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2021–0256 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–24196 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0260]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: ON THE JOB (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, Transportation (DOT).

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before December 6, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0260 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2021–0260 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0260, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email *James.Mead@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel ON THE JOB is:

—*Intended Commercial Use of Vessel:* ''Sunset cruises family.''
—*Geographic Region Including Base of Operations:* ''Florida.'' (Base of Operations: Fort Myers Beach, FL).
—*Vessel Length and Type:* 48.0′ Sail (Catamaran)

The complete application is available for review identified in the DOT docket as MARAD 2021–0260 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given

in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2021–0260 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

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By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–24200 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. OST–2021–0143]

Privacy Act of 1974; System of Records

AGENCY: Office of the Departmental Chief Information Office, Office of the Secretary of Transportation, DOT.

ACTION: Rescindment of a System of Records notice.

SUMMARY: The Office of the Secretary proposes to rescind the Department of Transportation system of records titled, ''Department of Transportation/ALL (DOT/ALL) 20 *On-line Accommodation Tracking System (OATS)* System of Records''.

DATES: *Applicable date:* November 5, 2021.

ADDRESSES: You may submit comments, identified by docket number OST–2021–0143 by any of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251. Instructions: You must include the agency name and docket number OST–2021–0143. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or to the street address listed above. Follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Karyn Gorman, Acting Departmental Chief Privacy Officer, Privacy Office, Department of Transportation, Washington, DC 20590; *privacy@dot.gov;* or 202.527.3284.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Transportation (DOT)/Federal Aviation Administration (FAA) proposes to rescind DOT system of records titled, ''Department of Transportation/ALL (DOT/ALL) On-line Accommodation Tracking System (OATS) System of Records,'' 74 FR 46637 (September 10, 20009). This system of records was established to facilitate the provision of reasonable accommodations to individuals with disabilities by establishing procedures, timeframes and forms for supervisors/decision makers to use in processing requests from employees and applicants for employment. The categories of records included employee's or applicant's name, functional limitation caused by the disability, reasonable accommodation (RA) requested, explanation of how RA would assist the applicant in the application process or the employee in performing his/her job or receiving the benefits and privileges of employment, dates when the required interactive discussions were held, notes from discussion regarding the request, action by deciding official, whether medical documentation was sought, justification for requesting medical documentation, any sources of technical assistance that were consulted, and if the request was denied, the reason for denial (but not medical documentation, which will be kept in a separate file). Non-PII in the system included: The employee's or applicant's occupational

series and grade or pay equivalent, operating administration, division or office, position title, office location and address and office telephone number; and the deciding official's name, title and office telephone number. The authority for maintenance of the system was the Rehabilitation Act of 1973, as amended, 29 U.S.C. 791; Executive Order 13164. The Department of Transportation determined that the Online Accommodations Tracking System (OATS) is no longer in use. The Department plans to publish a new System of Records titled ''DOT/ALL 28; Employee Accommodations Files'' to cover medical and religious accommodations files. Rescindment will promote the overall streamlining and management of DOT Privacy Act systems of records.

SYSTEM NAME AND NUMBER:

Department of Transportation/ALL (DOT/ALL) 20 On-line Accommodation Tracking System (OATS).

HISTORY:

A full notice of this system of records, DOT/ALL 20 On-line Accommodation Tracking System (OATS) was published in the **Federal Register** on September 10, 2009, at 74 FR 46637.

Issued in Washington, DC.

Karyn Gorman,

Acting, Departmental Chief Privacy Officer.

[FR Doc. 2021–24156 Filed 11–4–21; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning requirements respecting the adoption or change of accounting method; extensions of time to make elections.

DATES: Written comments should be received on or before January 4, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Kerry Dennis, 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 should be directed to Kerry Dennis, at (202) 317–5751 or Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Requirements Respecting the Adoption or Change of Accounting Method; Extensions of Time To Make Elections.

OMB Number: 1545–1488.

Regulation Number: TD 8742.

Abstract: This final regulation provides the procedures for requesting an extension of time to make certain elections, including changes in accounting method and accounting period. In addition, the regulation provides the standards that the IRS will use in determining whether to grant taxpayers extensions of time to make these elections.

Current Actions: There is no change in the form or paperwork burden previously approved.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals, not-for-profit institutions, and farms.

Estimated Number of Respondents: 500.

Estimated Time per Respondent: 10 hrs.

Estimated Total Annual Burden Hours: 5,000.

The following paragraph applies to all 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 if 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: November 1, 2021.

Kerry L. Dennis,

Tax Analyst.

[FR Doc. 2021–24179 Filed 11–4–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for the Application for Filing Information Returns Electronically

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning the application for filing information returns electronically (FIRE).

DATES: Written comments should be received on or before January 4, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Kerry Dennis, 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 should be directed to Kerry Dennis, at (202) 317–5751 or Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Application for Filing Information Returns Electronically (FIRE).

OMB Number: 1545–0387.

Form Number: 4419.

Abstract: Under section 6011(e)(2)(a) of the Internal Revenue Code, any

person, including corporations, partnerships, individuals, estates, and trusts, who is required to file 250 or more information returns must file such returns magnetically or electronically. Payers required to file on magnetic media or electronically must complete Form 4419 to receive authorization to file.

Current Actions: There is no change to the form that would affect burden. The information collection is being submitted to renew the collection and correct a mathematical error in the former submissions burden computation.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit organizations, non-profit institutions, and Federal, State, local, or tribal governments.

Estimated Number of Respondents: 15,000.

Estimated Time per Respondent: 20 minutes.

Estimated Total Annual Burden Hours: 4,950.

The following paragraph applies to all 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 if 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: November 2, 2021.

Kerry L. Dennis,

Tax Analyst.

[FR Doc. 2021–24242 Filed 11–4–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0618]

Agency Information Collection Activity Under OMB Review: Application by Insured Terminally Ill Person for Accelerated Benefit

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), 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. 2900–0618''.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0618'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Application by Insured Terminally Ill Person for Accelerated Benefit, SGLV 8284.

OMB Control Number: 2900–0618.

Type of Review: Extension of a currently approved collection.

Abstract: VA has amended regulations for the Servicemembers' Group Life Insurance (SGLI) and Veterans' Group Life Insurance (VGLI) programs to add accelerated death benefit (Accelerated Benefit) provisions that permit terminally ill policyholders access to the death benefits of their policies before they die. Traditionally, an individual purchases life insurance in order to safeguard his or her dependents against major financial loss due to his or her death. Life insurance serves to replace the lost income of an insured and to provide for his or her final expenses. In recent years, the insurance industry has recognized the financial needs of terminally ill policyholders and has begun offering policies with accelerated benefit provisions. A recent statutory amendment (Section 302 of the Veterans Programs Enhancement Act of 1998, Pub. L. 105–368, 112 Stat. 3315, 3332–3333) added section 1980 to Title 38, United States Code, which extends and accelerated benefit option to terminally ill persons insured in the SGLI and VGLI programs.

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 86 FR 161 on August 24, 2021, pages 47374 and 47375.

Affected Public: Individuals or Households.

Estimated Annual Burden: 40 hours.

Estimated Average Burden per Respondent: 12 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 200.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2021–24223 Filed 11–4–21; 8:45 am]

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Part II

Department of Labor

Occupational Safety and Health Administration

Department of Health and Human Services

Centers for Medicare & Medicaid Services

29 CFR Parts 1910, 1915, 1917, et al.

42 Parts 416, 418, 441, et al.

COVID–19 Vaccination and Testing; Emergency Temporary Standard; Medicare and Medicaid Programs; Omnibus COVID–19 Health Care Staff Vaccination; Interim Final Rules

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, 1926, and 1928

[Docket No. OSHA–2021–0007]

RIN 1218–AD42

COVID–19 Vaccination and Testing; Emergency Temporary Standard

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Interim final rule; request for comments.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is issuing an emergency temporary standard (ETS) to protect unvaccinated employees of large employers (100 or more employees) from the risk of contracting COVID–19 by strongly encouraging vaccination. Covered employers must develop, implement, and enforce a mandatory COVID–19 vaccination policy, with an exception for employers that instead adopt a policy requiring employees to either get vaccinated or elect to undergo regular COVID–19 testing and wear a face covering at work in lieu of vaccination.

DATES: The rule is effective November 5, 2021. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of November 5, 2021.

Compliance dates: Compliance dates for specific provisions are in 29 CFR 1910.501(m).

Comments: Written comments, including comments on any aspect of this ETS and whether this ETS should become a final rule, must be submitted by December 6, 2021 in Docket No. OSHA–2021–0007. Comments on the information collection determination described in *Additional Requirements* (Section V.K. of this preamble) (OMB review under the Paperwork Reduction Act of 1995) may be submitted by January 4, 2022 in Docket No. OSHA–2021–0008.

ADDRESSES: In accordance with 28 U.S.C. 2112(a), the Agency designates Edmund C. Baird, the Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, U.S. Department of Labor, to receive petitions for review of the ETS. Service can be accomplished by email to *zzSOL-Covid19-ETS@dol.gov.*

Written comments. You may submit comments and attachments, identified by Docket No. OSHA–2021–0007, electronically at *www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the online instructions for making electronic submissions.

Instructions: All submissions must include the agency's name and the docket number for this rulemaking (Docket No. OSHA–2021–0007). All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at *www.regulations.gov.* Therefore, OSHA cautions commenters about submitting information they do not want made available to the public, or submitting materials that contain personal information (either about themselves or others), such as Social Security Numbers and birthdates.

Docket: To read or download comments or other material in the docket, go to Docket No. OSHA–2021–0007 at *www.regulations.gov.* All comments and submissions are listed in the *www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through that website. All comments and submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Documents submitted to the docket by OSHA or stakeholders are assigned document identification numbers (Document ID) for easy identification and retrieval. The full Document ID is the docket number plus a unique four-digit code. OSHA is identifying supporting information in this ETS by author name and publication year, when appropriate. This information can be used to search for a supporting document in the docket at *http://www.regulations.gov.* Contact the OSHA Docket Office at 202–693–2350 (TTY number: 877–889–5627) for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

General information and press inquiries: Contact Frank Meilinger, OSHA Office of Communications, U.S. Department of Labor; telephone (202) 693–1999; email *OSHAComms@dol.gov.*

For technical inquiries: Contact Andrew Levinson, OSHA Directorate of Standards and Guidance, U.S. Department of Labor; telephone (202) 693–1950; email *ETS@dol.gov.*

SUPPLEMENTARY INFORMATION: The preamble to the ETS on COVID–19 vaccination and testing follows this outline:

Table of Contents

I. Executive Summary and Request for Comment

A. Executive Summary

This ETS is based on the requirements of the Occupational Safety and Health Act (OSH Act or Act) and legal precedent arising under the Act. Under section 6(c)(1) of the OSH Act, 29 U.S.C. 655(c)(1), OSHA shall issue an ETS if the agency determines that employees are subject to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and an ETS is necessary to protect employees from such danger. These legal requirements are more fully discussed in *Pertinent Legal Authority* (Section II. of this preamble). This ETS does not apply to workplaces subject to E.O. 14042 on Requiring Coronavirus Disease 2019 Vaccination for Federal Contractors. In addition, OSHA will treat federal agencies' compliance with E.O. 14043, and the Safer Federal Workforce Task Force guidance issued under section 4(e) of Executive Order 13991 and section 2 of Executive Order 14043, as sufficient to meet their obligations under the OSH Act and E.O. 12196.

COVID–19 has killed over 725,000 people in the United States in less than two years, and infected millions more (CDC, October 18, 2021—Cumulative US Deaths). The pandemic continues to affect workers and workplaces. While COVID–19 vaccines authorized or

approved by the U.S. Food and Drug Administration (FDA) effectively protect vaccinated individuals against severe illness and death from COVID–19, unvaccinated individuals remain at much higher risk of severe health outcomes from COVID–19. Further, unvaccinated workers are much more likely to contract and transmit COVID–19 in the workplace than vaccinated workers. OSHA has determined that many employees in the U.S. who are not fully vaccinated against COVID–19 face grave danger from exposure to SARS–CoV–2 in the workplace. This finding of grave danger is based on the severe health consequences associated with exposure to the virus along with evidence demonstrating the transmissibility of the virus in the workplace and the prevalence of infections in employee populations, as discussed in *Grave Danger* (Section III.A. of this preamble).

OSHA has also determined that an ETS is necessary to protect unvaccinated workers from the risk of contracting COVID–19 at work, as discussed in *Need for the ETS* (Section III.B. of this preamble). At the present time, workers are becoming seriously ill and dying as a result of occupational exposures to COVID–19, when a simple measure, vaccination, can largely prevent those deaths and illnesses. The ETS protects these workers through the most effective and efficient control available—vaccination—and further protects workers who remain unvaccinated through required regular testing, use of face coverings, and removal of all infected employees from the workplace. OSHA also concludes, based on its enforcement experience during the pandemic to date, that continued reliance on existing standards and regulations, the General Duty Clause of the OSH Act, 29 U.S.C. 654(a)(1), and workplace guidance, in lieu of an ETS, is not adequate to protect unvaccinated employees from the grave danger of being infected by, and suffering death or serious health consequences from, COVID–19.

OSHA will continue to monitor trends in COVID–19 infections and death as more of the workforce and the general population become fully vaccinated against COVID–19 and the pandemic continues to evolve. Where OSHA finds a grave danger from the virus no longer exists for the covered workforce (or some portion thereof), or new information indicates a change in measures necessary to address the grave danger, OSHA will update this ETS, as appropriate.

This ETS applies to employers with a total of 100 or more employees at any time the standard is in effect. In light of the unique occupational safety and health dangers presented by COVID–19, and against the backdrop of the uncertain economic environment of a pandemic, OSHA is proceeding in a stepwise fashion in addressing the emergency this rule covers. OSHA is confident that employers with 100 or more employees have the administrative capacity to implement the standard's requirements promptly, but is less confident that smaller employers can do so without undue disruption. OSHA needs additional time to assess the capacity of smaller employers, and is seeking comment to help the agency make that determination. Nonetheless, the agency is acting to protect workers now in adopting a standard that will reach two-thirds of all private-sector workers in the nation, including those working in the largest facilities, where the most deadly outbreaks of COVID–19 can occur.

The agency has also evaluated the feasibility of this ETS and has determined that the requirements of the ETS are both economically and technologically feasible, as outlined in *Feasibility* (Section IV. of this preamble). The specific requirements of the ETS are outlined and described in *Summary and Explanation* (Section VI. of this preamble).

B. Request for Comment

Although this ETS takes effect immediately, it also serves as a proposal under Section 6(b) of the OSH Act (29 U.S.C. 655(b)) for a final standard. Accordingly, OSHA seeks comment on all aspects of this ETS and whether it should be adopted as a final standard. OSHA encourages commenters to explain *why* they prefer or disfavor particular policy choices, and include any relevant studies, experiences, anecdotes or other information that may help support the comment. In particular, OSHA seeks comments on the following topics:

1. Employers with fewer than 100 employees. As noted above and fully discussed in the *Summary and Explanation* for *Scope and Application* (Section VI.B. of this preamble), OSHA has implemented a 100-employee threshold for the requirements of this standard to focus the ETS on companies that OSHA is confident will have sufficient administrative systems in place to comply quickly with the ETS. The agency is moving in a stepwise fashion on the short timeline necessitated by the danger presented by COVID–19 while soliciting stakeholder comment and additional information to determine whether to adjust the scope of the ETS to address smaller employers in the future. OSHA seeks information about the ability of employers with fewer than 100 employees to implement COVID–19 vaccination and/or testing programs. Have you instituted vaccination mandates (with or without alternatives), or requirements for regular COVID–19 testing or face covering use? What have been the benefits of your approach? What challenges have you had or could you foresee in implementing such programs? Is there anything specific to your industry, or the size of your business, that poses particular obstacles in implementing the requirements in this standard? How much time would it take, what types of costs would you incur, and how much would it cost for you to implement such requirements?

2. Significant Risk. If OSHA were to finalize a rule based on this ETS, it would be a standard adopted under 6(b) of the OSH Act, which requires a finding of significant risk from exposure to COVID–19. As discussed more fully in *Pertinent Legal Authority* (Section II. of this preamble), this is a lower showing of risk than grave danger, the finding required to issue a 6(c) emergency temporary standard. How should the scope of the rule change to address the significant risk posed by COVID–19 in the workplace? Should portions of the rule, such as face coverings, apply to fully vaccinated persons?

3. Prior COVID–19 infections. OSHA determined that workers who have been infected with COVID–19 but have not been fully vaccinated still face a grave danger from workplace exposure to SARS–CoV–2. This is an area of ongoing scientific inquiry. Given scientific uncertainty and limitations in testing for infection and immunity, OSHA is concerned that it would be infeasible for employers to operationalize a standard that would permit or require an exception from vaccination or testing and face covering based on prior infection with COVID–19. Is there additional scientific information on this topic that OSHA should consider as it determines whether to proceed with a permanent rule?

In particular, what scientific criteria can be used to determine whether a given employee is sufficiently protected against reinfection? Are there any temporal limits associated with this criteria to account for potential reductions in immunity over time? Do you require employees to provide verification of infection with COVID–19? If so, what kinds of verification do you accept (*i.e.,* PCR testing, antigen testing, etc.)? What challenges have you

experienced, if any, in operationalizing such an exception?

4. Experience with COVID–19 vaccination policies. Should OSHA impose a strict vaccination mandate (*i.e.,* all employers required to implement mandatory vaccination policies as defined in this ETS) with no alternative compliance option? OSHA seeks information on COVID–19 vaccination policies that employers have implemented to protect workers. If you have implemented a COVID–19 vaccination policy:

(a) When did you implement it, and what does your policy require? Was vaccination mandatory or voluntary under the policy? Do you offer vaccinations on site? What costs associated with vaccination did you cover under the policy? What percentage of your workforce was vaccinated as a result? Do you offer paid leave for receiving a vaccination? If vaccination is mandatory, have employees been resistant and if so what steps were required to enforce the policy?

(b) How did you verify that employees were vaccinated? Are there other reliable means of vaccination verification not addressed by the ETS that should be included? Did you allow attestation where the employee could not find other proof, and if so, have you experienced any difficulties with this approach? Have you experienced any issues with falsified records of vaccination, and if so, how did you deal with them?

(c) Have you experienced a decrease in infection rates or outbreaks after implementing this policy?

(d) If you have received any requests for reasonable accommodation from vaccination, what strategies did you implement to address the accommodation and ensure worker safety (*e.g.,* telework, working in isolation, regular testing and the use of face coverings)?

5. COVID–19 testing and removal. OSHA seeks information on COVID–19 testing and removal practices implemented to protect workers.

(a) Do you have a testing and removal policy in your workplace and, if so, what does it require? How often do you require testing and what types of testing do you use (*e.g.,* at-home tests, tests performed at laboratories, tests performed at your worksites)? What costs have you incurred as part of your testing and removal policies? Do you have difficulty in finding adequate availability of tests? How often? Have you experienced any issues with falsified test results, and if so, how did you deal with them? Have you experienced other difficulties in implementing a testing and removal scheme, including the length of time to obtain COVID–19 test results? Do you offer paid leave for testing?

(b) How often have you detected and removed COVID–19 positive employees from the workplace under this policy? Do you provide paid leave and job protection to employees you remove for this reason?

(c) Should OSHA require testing more often than on a weekly basis?

6. Face coverings. As discussed in the *Summary and Explanation* for *Face Coverings* (Section VI.I. of this preamble), ASTM released a specification standard on February 15, 2021, to establish a national standard baseline for barrier face coverings (ASTM F3502–21). Should OSHA require the use of face coverings meeting the ASTM F3502–21 standard instead of the face coverings specified by the ETS? If so, should OSHA also require that such face coverings meet the NIOSH Workplace Performance or Workplace Performance Plus criteria (see CDC, September 23, 2021)? Are there particular workplace settings in which face coverings meeting one standard should be favored over another? Are there alternative criteria OSHA should consider for face coverings instead of the F3502–21 standard or NIOSH Workplace Performance or Workplace Performance Plus criteria? Is there sufficient capacity to supply face coverings meeting F3502–01 and/or NIOSH Workplace Performance or Workplace Performance Plus criteria to all employees covered by the ETS? What costs have you incurred as part of supplying employees with face coverings meeting the appropriate criteria?

7. Other controls. This ETS requires employees to either be fully vaccinated against COVID–19 or be tested weekly and wear face coverings, based on the type of policy their employer adopts. It stops short of requiring the full suite of workplace controls against SARS–CoV–2 transmission recommended by OSHA and the CDC, including distancing, barriers, ventilation, and sanitation. As OSHA explained in *Need for the ETS* (Section III.B. of this preamble), OSHA has determined that it needs more information before imposing these requirements on the entire scope of industries and employers covered by the standard. OSHA is interested in hearing from employers about their experience in implementing a full suite of workplace controls against COVID–19.

What measures have you taken to protect employees against COVID–19 in your workplace? Are there controls that you attempted to employ but found ineffective or infeasible? What are they? Why did you conclude that they were they ineffective or infeasible; for example, are there particular aspects of your workplace or industry that make certain controls infeasible? Do you require both fully vaccinated and unvaccinated employees to comply with these controls? Have you experienced a reduction in infection rates or outbreaks since implementing these controls?

8. Educational materials. Have you implemented any policies or provided any information that has been helpful in encouraging an employee to be vaccinated?

9. Feasibility and health impacts. Do you have any experience or data that would inform OSHA's estimates in its economic feasibility analysis or any of the assumptions or estimates used in OSHA's identification of the number of hospitalizations prevented and lives saved from its health impacts analysis (see OSHA, October 2021c)?

References

Centers for Disease Control and Prevention (CDC). (2021, October 18). COVID Data Tracker. *https://covid.cdc.gov/covid-data-tracker/.* (CDC, October 18, 2021)

Centers for Disease Control and Prevention (CDC). (2021, September 23). Types of Masks and Respirators. *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html.* (CDC, September 23, 2021)

Occupational Safety and Health Administration (OSHA). (2021c, October). Health Impacts of the COVID–19 Vaccination and Testing ETS. (OSHA, October 2021c)

II. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act of 1970 (OSH Act), 29 U.S.C. 651 et seq., is ''to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources.'' 29 U.S.C. 651(b). To this end, Congress authorized the Secretary of Labor (Secretary) to promulgate and enforce occupational safety and health standards under sections 6(b) and (c) of the OSH Act.[1] 29 U.S.C. 655(b). These provisions provide bases for issuing occupational safety and health standards under the Act. Once OSHA has established as a threshold matter that a health standard is necessary under section 6(b) or (c)—*i.e.,* to reduce

[1] The Secretary has delegated most of his duties under the OSH Act to the Assistant Secretary of Labor for Occupational Safety and Health. Secretary's Order 08–2020, 85 FR 58393 (Sept. 18, 2020). This section uses the terms Secretary and OSHA interchangeably.

a significant risk of material health impairment, or a grave danger to employee health—the Act gives the Secretary ''almost unlimited discretion to devise means to achieve the congressionally mandated goal'' of protecting employee health, subject to the constraints of feasibility. See *United Steelworkers of Am.* v. *Marshall,* 647 F.2d 1189, 1230 (D.C. Cir. 1981). A standard's individual requirements need only be ''reasonably related'' to the purpose of ensuring a safe and healthful working environment. Id. at 1237, 1241; see also *Forging Indus. Ass'n* v. *Sec'y of Labor,* 773 F.2d 1436, 1447 (4th Cir. 1985). OSHA's authority to regulate employers is hedged by constitutional considerations and, pursuant to section 4(b)(1) of the OSH Act, the regulations and enforcement policies of other federal agencies. See, *e.g., Chao* v. *Mallard Bay Drilling, Inc.,* 534 U.S. 235, 241 (2002).

The OSH Act in section 6(c)(1) states that the Secretary ''shall'' issue an emergency temporary standard (ETS) upon a finding that the ETS is necessary to address a grave danger to workers. See 29 U.S.C. 655(c). In particular, the Secretary shall provide, without regard to the requirements of chapter 5, title 5, United States Code, for an emergency temporary standard to take immediate effect upon publication in the **Federal Register** if the Secretary makes two determinations: That employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and that such emergency standard is necessary to protect employees from such danger. 29 U.S.C. 655(c)(1). A separate section of the OSH Act, section 8(c), authorizes the Secretary to prescribe regulations requiring employers to make, keep, and preserve records that are necessary or appropriate for the enforcement of the Act. 29 U.S.C. 657(c)(1). Section 8(c) also provides that the Secretary shall require employers to keep records of, and report, work-related deaths and illnesses. 29 U.S.C. 657(c)(2).

The ETS provision, section 6(c)(1), exempts the Secretary from procedural requirements contained in the OSH Act and the Administrative Procedure Act, including those for public notice, comments, and a rulemaking hearing. See, *e.g.,* 29 U.S.C. 655(b)(3); 5 U.S.C. 552, 553.

The Secretary must issue an ETS in situations where employees are exposed to a ''grave danger'' and immediate action is necessary to protect those employees from such danger. 29 U.S.C. 655(c)(1); *Pub. Citizen Health Research Grp.* v. *Auchter,* 702 F.2d 1150, 1156 (D.C. Cir. 1983). The determination of what exact level of risk constitutes a ''grave danger'' is a ''policy consideration that belongs, in the first instance, to the Agency.'' *Asbestos Info. Ass'n,* 727 F.2d at 425 (accepting OSHA's determination that eighty lives at risk over six months was a grave danger); *Indus. Union Dep't, AFL–CIO* v. *Am. Petroleum Inst.,* 448 U.S. 607, 655 n.62 (1980). However, a ''grave danger'' represents a risk greater than the ''significant risk'' that OSHA must show in order to promulgate a permanent standard under section 6(b) of the OSH Act, 29 U.S.C. 655(b). *Int'l Union, United Auto., Aerospace, & Agr. Implement Workers of Am., UAW* v. *Donovan,* 590 F. Supp. 747, 755–56 (D.D.C. 1984), adopted, 756 F.2d 162 (D.C. Cir. 1985); see also Indus. Union Dep't, AFL–CIO, 448 U.S. at 640 n.45 (noting the distinction between the standard for risk findings in permanent standards and ETSs).

In determining the type of health effects that may constitute a ''grave danger'' under the OSH Act, the Fifth Circuit emphasized ''the danger of incurable, permanent, or fatal consequences to workers, as opposed to easily curable and fleeting effects on their health.'' *Fla. Peach Growers Ass'n, Inc.* v. *U. S. Dep't of Labor,* 489 F.2d 120, 132 (5th Cir. 1974). Although the findings of grave danger and necessity must be based on evidence of ''*actual,* prevailing industrial conditions,'' see *Int'l Union,* 590 F. Supp. at 751, when OSHA determines that exposure to a particular hazard would pose a grave danger to workers, OSHA can assume an exposure to a grave danger wherever that hazard is present in a workplace. *Dry Color Mfrs. Ass'n, Inc.* v. *Dep't of Labor,* 486 F.2d 98, 102 n.3 (3d Cir. 1973).

In demonstrating whether OSHA had shown that an ETS is necessary, the Fifth Circuit considered whether OSHA had another available means of addressing the risk that would not require an ETS. *Asbestos Info. Ass'n,* 727 F.2d at 426 (holding that necessity had not been proven where OSHA could have increased enforcement of already-existing standards to address the grave risk to workers from asbestos exposure). Additionally, a standard must be both economically and technologically feasible in order to be ''reasonably necessary and appropriate'' under section 3(8) and, by inference, ''necessary'' under section 6(c)(1)(B) of the Act. *Cf. Am. Textile Mfrs. Inst., Inc.* v. *Donovan,* 452 U.S. 490, 513 n.31 (1981) (noting ''any standard that was not economically or technologically feasible would *a fortiori* not be 'reasonably necessary or appropriate' '' as required by the OSH Act's definition of ''occupational safety and health standard'' in section 3(8)); see also *Florida Peach Growers,* 489 F.2d at 130 (recognizing that the promulgation of any standard, including an ETS, must account for its economic effect). However, given that section 6(c) is aimed at enabling OSHA to protect workers in emergency situations, the agency is not required to make a feasibility showing with the same rigor as in ordinary section 6(b) rulemaking. *Asbestos Info. Ass'n,* 727 F.2d at 424 n.18.

On judicial review of an ETS, OSHA is entitled to great deference on the determinations of grave danger and necessity required under section 6(c)(1). See, *e.g., Pub. Citizen Health Research Grp.,* 702 F.2d at 1156; *Asbestos Info. Ass'n,* 727 F.2d at 422 (judicial review of these legislative determinations requires deference to the agency); cf. *Am. Dental Ass'n* v. *Martin,* 984 F.2d 823, 831 (7th Cir. 1993) (''the duty of a reviewing court of generalist judges is merely to patrol the boundary of reasonableness''). These determinations are ''essentially legislative and rooted in inferences from complex scientific and factual data.'' *Pub. Citizen Health Research Grp.,* 702 F.2d at 1156. The agency is not required to support its conclusions ''with anything approaching scientific certainty,'' *Indus. Union Dep't, AFL–CIO,* 448 U.S. at 656, and has the ''prerogative to choose between conflicting evidence.'' *Asbestos Info. Ass'n,* 727 F.2d at 425.

The determinations of the Secretary in issuing standards under section 6 of the OSH Act, including ETSs, must be affirmed if supported by ''substantial evidence in the record considered as a whole.'' 29 U.S.C. 655(f). The Supreme Court described substantial evidence as ''such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'' *Am. Textile Mfrs. Inst.,* 452 U.S. at 522–23 (quoting *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 477 (1951)). The Court also noted that ''the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence.'' Id. at 523 (quoting *Consolo* v. *FMC,* 383 U.S. 607, 620 (1966)). The Fifth Circuit, recognizing the size and complexity of the rulemaking record before it in the case of OSHA's ETS for organophosphorus pesticides, stated that a court's function in reviewing an ETS to determine whether it meets the substantial evidence standard is ''basically [to] determine whether the

Secretary carried out his essentially legislative task in a manner reasonable under the state of the record before him.'' *Fla Peach Growers Ass'n,* 489 F.2d at 129.

Although Congress waived the ordinary rulemaking procedures in the interest of ''permitting rapid action to meet emergencies,'' section 6(e) of the OSH Act, 29 U.S.C. 655(e), requires OSHA to include a statement of reasons for its action when it issues any standard. *Dry Color Mfrs.,* 486 F.2d at 105–06 (finding OSHA's statement of reasons inadequate). By requiring the agency to articulate its reasons for issuing an ETS, the requirement acts as ''an essential safeguard to emergency temporary standard-setting.'' Id. at 106. However, the Third Circuit noted that it did not require justification of ''every substance, type of use or production technique,'' but rather a ''general explanation'' of why the standard is necessary. Id. at 107.

ETSs are, by design, temporary in nature. Under section 6(c)(3), an ETS serves as a proposal for a permanent standard in accordance with section 6(b) of the OSH Act (permanent standards), and the Act calls for the permanent standard to be finalized within six months after publication of the ETS. 29 U.S.C. 655(c)(3); see *Fla. Peach Growers Ass'n,* 489 F.2d at 124. The ETS is effective ''until superseded by a standard promulgated in accordance with'' section 6(c)(3). 29 U.S.C. 655(c)(2).

Section 6(c)(1) states that the Secretary ''shall'' provide for an ETS when OSHA makes the prerequisite findings of grave danger and necessity. See *Pub. Citizen Health Research Grp.,* 702 F.2d at 1156 (noting the mandatory language of section 6(c)). OSHA is entitled to great deference in its determinations, and it must also account for ''the fact that 'the interests at stake are not merely economic interests in a license or a rate structure, but personal interests in life and health.' '' Id. (quoting *Wellford* v. *Ruckelshaus,* 439 F.2d 598, 601 (D.C. Cir. 1971)).

When OSHA issues a standard pursuant to section 6—whether permanent or an ETS—section 18 of the OSH Act provides that OSHA's standard preempts any state occupational safety or health standard ''relating to [the same] occupational safety or health issue'' as the Federal standard. 29 U.S.C. 667(b); see also *Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 97 (1992). A state can avoid preemption only if it submits, and receives Federal approval for, a state plan for the development and enforcement of standards pursuant to section 18 of the Act, which must be ''at least as effective'' as the Federal standards. 29 U.S.C. 667; *Indus. Truck Ass'n* v. *Henry*, 125 F.3d 1305, 1311 (9th Cir. 1997). However, the OSH Act does not preempt state laws of ''general applicability'' that regulate workers and non-workers alike, so long as they do not conflict with an OSHA standard. *Gade*, 505 U.S. at 107.

As discussed in detail elsewhere in this preamble, OSHA has determined that a grave danger exists necessitating a new ETS (see *Grave Danger* and *Need for the ETS*, Sections III.A. and III.B. of this preamble), and that compliance with this ETS is feasible for covered employers (see *Feasibility*, Section IV. of this preamble). OSHA has also provided a more detailed explanation of each provision of this ETS in *Summary and Explanation* (Section VI. of this preamble). In addition, OSHA wishes to provide here some general guidance on its legal authority to regulate COVID–19 hazards, and for particular provisions of this ETS.

As a threshold matter, OSHA's authority to regulate workplace exposure to biological hazards like SARS–CoV–2 is well-established. Section 6(b)(5) of the OSH Act uses similar language to section 6(c)(1)(A): The former sets forth requirements for promulgating permanent standards addressing ''toxic materials or harmful physical agents,'' and the latter authorizes OSHA to promulgate an ETS addressing ''substances or agents determined to be toxic or physically harmful'' (as well as ''new hazards''). OSHA has consistently identified biological hazards similar to SARS–CoV–2, as well as SARS–CoV–2 itself, to be ''toxic materials or harmful physical agents'' under the Act. Indeed, in its exposure and medical records access regulation, OSHA has defined ''toxic materials or harmful physical agents'' to include ''any . . . biological agent (bacteria, virus, fungus, etc.)'' for which there is evidence that it poses a chronic or acute health hazard. 29 CFR 1910.1020(c)(13). And in addition to previously regulating exposure to SARS–CoV–2 as a new and physically harmful agent in the Healthcare ETS (see, *e.g.*, 86 FR at 32381), OSHA has also previously regulated biological hazards like SARS–CoV–2 as health hazards under section 6(b)(5), for example in the Bloodborne Pathogens (BBP) standard, 29 CFR 1910.1030, which addresses workplace exposure to HIV and Hepatitis B. The BBP standard was upheld (except as to application in certain limited industries) in *American Dental Association*, which observed that ''the infectious character'' of the regulated bloodborne diseases might warrant ''more regulation than would be necessary in the case of a noncommunicable disease.'' 984 F.2d at 826. In addition, in the preamble to the respiratory protection standard, 29 CFR 1910.134, which was also promulgated under section 6(b)(5), ''OSHA emphasize[d] that [the] respiratory protection standard does apply to biological hazards.'' Respiratory Protection, 63 FR 1152–01, 1180 (Jan. 8, 1998) (citing *Mahone Grain Corp.,* 10 BNA OSHC 1275 (No. 77–3041, 1981)).

In addition to being a physically harmful agent covered by section 6(c)(1)(A), SARS–CoV–2 is also, without question, a ''new hazard'' covered by this provision, as discussed in more detail in *Grave Danger* (Section III.A. of this preamble). SARS–CoV–2 was not known to exist until January 2020, and since then more than 725,000 people have died from COVID–19 in the U.S. alone (CDC, October 18, 2021—Cumulative US Deaths).

Turning to specific provisions of this standard, the vaccination requirements in this ETS are also well within the bounds of OSHA's authority. Vaccination can be a critical tool in the pursuit of health and safety goals, particularly in response to an infectious and highly communicable disease. See, *e.g.*, *Jacobson* v. *Commonwealth of Mass.*, 197 U.S. 11, 27–28 (1905) (recognizing use of smallpox vaccine as a reasonable measure to protect public health and safety); *Klaassen* v. *Trustees of Ind. Univ.*, 7 F.4th 592, 593 (7th Cir. 2021) (citing *Jacobson* and noting that vaccination may be an appropriate safety measure against SARS–CoV–2 as ''[v]accination protects not only the vaccinated persons but also those who come in contact with them''). And the OSH Act itself explicitly acknowledges that such treatments might be necessary, in some circumstances. 29 U.S.C. 669(a)(5) (providing in the Act's provisions on research and related activities conducted by the Secretary of Health and Human Services to aid OSHA in its formulation of health and safety standards that ''[n]othing in this or any other provision of this Act shall be deemed to authorize or require medical examination, *immunization*, or treatment for those who object thereto on religious grounds, *except where such is necessary for the protection of the health or safety of others.*'' (emphasis added)). In recognition of the health and safety benefits provided by vaccination, OSHA has previously exercised its authority to promulgate vaccine-related requirements in the COVID–19 Healthcare ETS (29 CFR 1910.502(m))

and the BBP standard (29 CFR 1910.1030(f)). The BBP standard illustrates congressional understanding that the statutory delegation of authority to OSHA to issue standards includes authority for vaccine provisions, where appropriate. See Public Law 102–170, Title I, Section 100, 105 Stat. 1107 (1991) (directing OSHA to complete the BBP rulemaking by a date certain, and providing that if OSHA did not do so, the proposed rule, which included a vaccine provision, would become the final standard).

Additionally, OSHA's authority to require employers to bear the costs of particular provisions of a standard is solidly grounded in the OSH Act. The Act reflects Congress's determination that the costs of compliance with the Act and OSHA standards are part of the cost of doing business and OSHA may foreclose employers from shifting those costs to employees. See *Am. Textile Mfrs. Inst.*, 452 U.S. at 514; *Phelps Dodge Corp.* v. *OSHRC*, 725 F.2d 1237, 1239–40 (9th Cir. 1984); see also *Sec'y of Labor* v. *Beverly Healthcare-Hillview*, 541 F.3d 193 (3d Cir. 2008). Consistent with this authority, OSHA has largely required employers to bear the costs of the provisions of this ETS, including the typical costs associated with vaccination. The allocation of vaccination costs to employers in this ETS is similar to OSHA's treatment of vaccine-related costs in the COVID–19 Healthcare ETS and the BBP standards. See 29 CFR 1910.502(m), (p); 29 CFR 1910.1030(f)(1)(ii)(A).

The OSH Act provides OSHA with discretion, however, to decide whether to impose certain costs—such as those related to medical examinations or other tests—on employers ''[w]here [it determines that such costs are] appropriate.'' 29 U.S.C. 655(b)(7). OSHA has determined that for purposes of this ETS, it would not be ''appropriate'' to impose on employers any costs associated with COVID–19 testing for employees who choose not to be vaccinated. For most of the agency's existing standards containing medical testing and removal provisions, OSHA has found it necessary to impose the costs of such provisions on employers in order to remove barriers to employee participation in medical examinations that are critical to effectuating the standards' safety and health protections. See *United Steelworkers of Am.*, 647 F.2d at 1229–31, 1237–38. However, as explained in greater detail elsewhere in this preamble (see *Need for the ETS*, Section III.B. of this preamble), the ETS's safety and health protections are best effectuated by employee vaccination, not testing. Accordingly, OSHA only requires employers to bear the costs of employee compliance with the preferred, and more protective, vaccination provision, but not costs associated with testing. The agency does not believe it appropriate to impose the costs of testing on an employer where an employee has made an individual choice to pursue a less protective option. For the same reasons, OSHA has also determined that it is not appropriate to require employers to pay for face coverings for employees who choose not to be vaccinated.[2]

Finally, the Act and its legislative history ''both demonstrate unmistakably'' OSHA's authority to require employers to temporarily remove workers from the workplace to prevent exposure to a health hazard. *United Steelworkers of Am.*, 647 F.2d at 1230. And again, this is an authority OSHA has repeatedly exercised in prior standards, including in: COVID–19 Healthcare ETS (29 CFR 1910.502); Lead (29 CFR 1910.1025); Cadmium (29 CFR 1910.1027); Benzene (29 CFR 1910.1028); Formaldehyde (29 CFR 1910.1048); Methylenedianiline (29 CFR 1910.1050); Methylene Chloride (29 CFR 1910.1052); and Beryllium (29 CFR 1910.1024). It is equally appropriate to impose that obligation here.

For all of these reasons, as well as those explained more fully in other areas of this preamble, OSHA has the authority—and obligation—to promulgate this ETS.

References

Centers for Disease Control and Prevention (CDC). (2021, October 18). COVID Data Tracker. *https://covid.cdc.gov/covid-data-tracker/.* (CDC, October 18, 2021)

III. Rationale for the ETS

A. Grave Danger

I. Introduction

Section 6(c)(1) of the OSH Act requires the Secretary to issue an ETS in situations where employees are exposed to a ''grave danger'' and immediate action is necessary to protect those employees from such danger (29 U.S.C. 655(c)(1)). Consistent with its legal duties, OSHA is issuing this ETS to address the grave danger posed by occupational exposure to SARS–CoV–2, the virus that causes COVID–19.[3] OSHA has determined that occupational exposure to SARS–CoV–2, including the Delta variant (B.1.617.2 and AY lineages), presents a grave danger to unvaccinated workers in the U.S., with several exceptions explained below.[4] This finding of grave danger is based on the science of how the virus spreads, the transmissibility of the disease in workplaces, and the serious adverse health effects, including death, that can be suffered by those who are diagnosed with COVID–19. The protections of this ETS—which will apply, with some limitations, to a broad range of workplace settings where exposure to SARS–CoV–2 may occur—are designed to protect employees from infection with SARS–CoV–2 and from the dire, sometimes fatal, consequences of such infection.

The fact that COVID–19 is not a uniquely work-related hazard does not change the determination that it is a grave danger to which employees are exposed, nor does it excuse employers from their duty to protect employees from the occupational transmission of SARS–CoV–2. The OSH Act is intended to ''assure so far as possible every working man and woman in the Nation safe and healthful working conditions'' (29 U.S.C. 651(b)), and there is nothing in the Act to suggest that its protections do not extend to hazards which might occur outside of the workplace as well as within. Indeed, COVID–19 is not the first hazard that OSHA has regulated that occurs both inside and outside the workplace. For example, the hazard of noise is not unique to the workplace, but the Fourth Circuit has upheld OSHA's Occupational Noise Exposure standard (29 CFR 1910.95) (*Forging Industry Ass'n* v. *Sec' of Labor*, 773 F.2d 1437, 1444 (4th Cir. 1985)). Diseases caused by bloodborne pathogens, including HIV/AIDS and hepatitis B, are also not unique to the workplace, but the Seventh Circuit upheld the majority of OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) (*Am. Dental Ass'n* v. *Martin*, 984 F.2d 823 (7th Cir. 1993)). OSHA's Sanitation

[2] OSHA notes that while the ETS does not impose these testing or face covering costs on employers, in some circumstances employers may be required to pay for the costs related to testing and/or face coverings by other laws, regulations, or collectively negotiated agreements. OSHA has no authority under the OSH Act to determine whether such obligations under other laws, regulations, or agreements might exist.

[3] OSHA is defining the grave danger as workplace exposure to SARS–CoV–2, the virus that causes the development of COVID–19. COVID–19 is the disease that can occur in people exposed to SARS-CoV–2, and that leads to the health effects described in this section. This distinction applies despite OSHA's use of the terms SARS–CoV–2 and COVID–19 interchangeably in some parts of this preamble.

[4] OSHA refers to the grave danger from occupational exposure to SARS–CoV–2 throughout this document. Those references are intended to encompass exposure to SARS–CoV–2 and all variants of SARS–CoV–2, including the Delta variant.

standard, 29 CFR 1910.141, which requires measures such as cleaning, waste disposal, potable water, toilets, and washing facilities, addresses hazards that exist everywhere—both within and outside of workplaces. Moreover, employees have more freedom to control their environment outside of work, and to make decisions about their behavior and their contact with others to better minimize their risk of exposure. However, during the workday, while under the control of their employer, workers may have little ability to limit contact with coworkers, clients, members of the public, patients, and others, any one of whom could represent a source of exposure to SARS–CoV–2. OSHA has a mandate to protect employees from hazards they are exposed to at work, even if they may be exposed to similar hazards outside of work.

As described above in *Pertinent Legal Authority* (Section II. of this preamble), ''grave danger'' indicates a risk that is more than ''significant'' (*Int'l Union, United Auto., Aerospace, & Agr. Implement Workers of Am., UAW* v. *Donovan*, 590 F. Supp. 747, 755–56 (D.D.C. 1984); *Indus. Union Dep't, AFL–CIO* v. *Am. Petroleum Inst.*, 448 U.S. 607, 640 n.45, 655 (1980) (stating that a rate of 1 worker in 1,000 workers suffering a given health effect constitutes a ''significant'' risk)). ''Grave danger,'' according to one court, refers to ''the danger of incurable, permanent, or fatal consequences to workers, as opposed to easily curable and fleeting effects on their health'' (*Fla. Peach Growers Ass'n, Inc.* v. *U.S. Dep't of Labor*, 489 F.2d 120, 132 (5th Cir. 1974)). Fleeting effects were described as nausea, excessive salivation, perspiration, or blurred vision and were considered so minor that they often went unreported; these effects are in stark contrast with the adverse health effects of COVID–19 infections, which are formally referenced as ranging from ''mild'' to ''critical,'' [5] but which can involve significant illness, hospital stays, ICU care, death, and long-term health complications for survivors. Beyond this, however, ''the determination of what constitutes a risk worthy of Agency action is a policy consideration that belongs, in the first instance, to the Agency'' (*Asbestos Info. Ass'n/N. Am.* v. *OSHA*, 727 F.2d 415, 425 (5th Cir. 1984)).

In the context of ordinary 6(b) rulemaking, the Supreme Court has said that the OSH Act is not a ''mathematical straitjacket,'' nor does it require the agency to support its findings ''with anything approaching scientific certainty,'' particularly when operating on the ''frontiers of scientific knowledge'' (*Indus. Union Dep't, AFL–CIO* v. *Am. Petroleum Inst.*, 448 U.S. 607, 655–56 (1980)). Courts reviewing OSHA's determination of grave danger do so with ''great deference'' (*Pub. Citizen Health Research Grp.* v. *Auchter*, 702 F.2d 1150, 1156 (D.C. Cir. 1983)). In one case, the Fifth Circuit, in reviewing an OSHA ETS for asbestos, declined to question the agency's finding that 80 worker lives at risk nationwide over six months constituted a grave danger (*Asbestos Info. Ass'n/N. Am.*, 727 F.2d at 424). OSHA estimates that this ETS would save over 6,500 worker lives and prevent over 250,000 hospitalizations over the course of the next six months (OSHA, October 2021c). Here, the mortality and morbidity risk to employees from COVID–19 is so dire that the grave danger from exposures to SARS–CoV–2 is clear.

SARS–CoV–2 is both a physically harmful agent and a new hazard (see 29 U.S.C. 655(c)(1)(A)). The majority of OSHA's previous ETSs addressed toxic substances that had been familiar to the agency for many years prior to issuance of the ETS. OSHA's Healthcare ETS, issued in response to COVID–19 earlier this year, is one notable exception. In most cases, OSHA's ETSs were issued in response to new information about substances that had been used in workplaces for decades (*e.g.*, Vinyl Chloride (39 FR 12342 (April 5, 1974)); Benzene (42 FR 22516 (May 3, 1977)); 1,2-Dibromo-3-chloropropane (42 FR 45536 (Sept. 9, 1977))). In some cases, the hazards of the toxic substance were already so well established that OSHA promulgated an ETS simply to update an existing standard (*e.g.*, Vinyl cyanide (43 FR 2586 (Jan. 17, 1978))). The COVID–19 Healthcare ETS, which was issued in June 2021, was the sole instance in which OSHA issued an ETS to address a grave danger from a substance that had only recently come into existence. Although that action by the agency was challenged, the case has not gone to briefing (see *United Food & Commercial Workers Int'l Union, AFL–CIO, CLC and AFL–CIO* v. *OSHA, Dep't of Labor*, D.C. Circuit No. 21–1143). Thus, no court has had occasion to examine OSHA's authority under section (6)(c) of the OSH Act (29 U.S.C. 655(c)) to address a grave danger from a ''new hazard.'' Yet by any measure, SARS–CoV–2 is a new hazard. Unlike any of the hazards addressed in previous ETSs, there were no documented cases of SARS–CoV–2 infections in the United States until January 2020. Since then, more than 725,000 people have died in the U.S. alone (CDC, October 18, 2021—Cumulative US Deaths). The pandemic continues to affect workers and workplaces, with workplace exposures leading to further exposures among workers' families and communities. Clearly, SARS–CoV–2 is both a physically harmful agent and a new hazard that presents a grave danger to workers in the U.S.

Published on June 21, 2021, OSHA's Healthcare ETS (86 FR 32376) was written in response to the grave danger posed to healthcare workers in the United States who faced a heightened risk of infection from COVID–19. In the healthcare ETS, OSHA described its finding of grave danger for healthcare and healthcare support service workers (see 86 FR 32381–32412). OSHA now finds that all unvaccinated workers, with some exceptions, face a grave danger from the SARS–CoV–2 virus.[6]

II. Nature of the Disease

The health effects of symptomatic COVID–19 illness can range from mild disease consisting of fever or chills, cough, and shortness of breath to severe disease. Severe cases can involve respiratory failure, blood clots, long-term cardiovascular and neurological effects, and organ damage, which can lead to hospitalization, ICU admission, and death (see 86 FR 32383–32388; NINDS, September 2, 2021). Even in the short time since the Healthcare ETS's publication in June 2021, the risk posed by COVID–19 has changed meaningfully. Since OSHA considered the impact of COVID–19 when promulgating the Healthcare ETS, over 135,000 additional Americans have died from COVID–19, and over 933,000 have been hospitalized, (CDC, October 18, 2021—Cumulative US Deaths; CDC, May 28, 2021; CDC, October 18, 2021—Weekly Review). In August 2021, COVID–19 was the third leading cause of death in the United States, trailing only heart disease and cancer (Ortaliza et al., August 27, 2021). By September 20, 2021, COVID–19 had killed as many Americans as the 1918–1919 flu pandemic (Johnson, September 20, 2021).

While the Healthcare ETS addresses the risk of illness and death from

[5] See the definitions for the different levels of severity of COVID–19 illness in the National Institutes of Health's COVID–19 treatment guidelines (NIH, October 12, 2021).

[6] When OSHA refers to ''unvaccinated'' individuals in its grave danger finding, it means all individuals who are not fully vaccinated against COVID–19, *i.e.*, those who are completely unvaccinated and those who are partially vaccinated.

COVID–19 as the SARS–CoV–2 virus continues to change over time, it does not specifically address the increases in infectiousness and transmission, and the potentially more severe health effects, related to the Delta variant. The rapid rise to predominance of the Delta variant in the U.S. occurred shortly after the ETS was published. At this time, the widespread prevalence of the Delta variant and its increased transmissibility have resulted in increased risk of exposure and disease relative to the previously-dominant strains of the SARS–CoV–2 virus. Adding to the information covered in the Healthcare ETS, the following sections provide a brief review of SARS–CoV–2 and describe the characteristics of the Delta variant that are different from previous versions of SARS–CoV–2 and have changed the risks posed by COVID–19. The agency specifically references the material presented in the Healthcare ETS, which is still relevant to this analysis, to support OSHA's finding of grave danger. Taken together, the information available to OSHA demonstrates that SARS–CoV–2 poses a grave danger to unvaccinated workers across all industry sectors.

a. Variants of SARS–CoV–2

Viral mutations have been a serious concern of scientists, public health experts, and policymakers from the beginning of the COVID–19 pandemic. Viral mutations can affect how a virus interacts with a cell—altering the virus's transmissibility, infection severity, and sensitivity to vaccines. The U.S. government's SARS–CoV–2 Interagency Group has a variant classification scheme that defines four classes of SARS–CoV–2 variants: Variants Being Monitored (VBM), Variants of Interest (VOI), Variants of Concern (VOC), and Variants of High Consequence (VOHC). These variant designations are based on their ''proportions at the national and regional levels and the potential or known impact of the constellation of mutations on the effectiveness of medical countermeasures, severity of disease, and ability to spread from person to person'' (CDC, October 4, 2021), with VOIs considered less serious than VOCs and VOCs considered less serious than VOHCs. As of early October 2021, the CDC was monitoring 10 VBMs—Alpha (B.1.1.7, Q.1–Q.8), Beta (B.1.351, B.1.351.2, B.1.351.3), Gamma (P.1, P.1.1, P.1.2), Epsilon (B.1.427 and B.1.429), Eta (B.1.525), Iota (B.1.526), Kappa (B.1.617.1), B.1.617.3, Mu (B.1.621, B.1.621.1), and Zeta (P.2)—and one VOC—Delta (B.1.617.2 and AY.1 sublineages)—in the U.S. (CDC, October 4, 2021). CDC defines a VOC as ''[a] variant for which there is evidence of an increase in transmissibility, more severe disease (*e.g.*, increased hospitalizations or deaths), significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures'' (CDC, October 4, 2021).

While the proportions of SARS–CoV–2 variants in the United States have shifted over time (CDC, May 24, 2021c; CDC, October 18, 2021—Variant Proportions, July through October 2021), the primary variant that drove COVID–19 transmission in the late Winter and Spring of 2021 was the Alpha variant. The CDC noted that Alpha is associated with an increase in transmission, as well as potentially increased incidences of hospitalization and death, compared to the predominant variants before its emergence (CDC, October 4, 2021; Pascall et al., August 24, 2021; Julin et al., September 22, 2021). As Alpha transmission subsided in the United States during the late Spring and early Summer of 2021, Delta emerged and quickly became the predominant variant in the U.S. by July 3, 2021 (CDC, October 18, 2021—Variant Proportions, July through October 2021). Delta now accounts for more than 99% of circulating virus nationwide (CDC, October 18, 2021—Variant Proportions, July through October 2021).

FDA authorized and approved COVID–19 vaccines currently work well against all of these variants; however, there are differences in various variants' ability to spread and the likelihood of infection to cause severe illness. Data on the Beta and Gamma variants do not indicate that infections from these variants caused more severe illness or death than other VOCs. Data on the Alpha variant does indicate its ability to cause more severe illness and death in infected individuals. And some data on the Delta variant suggests that the Delta variant may cause more severe illness than previous variants, including Alpha, in unvaccinated individuals (CDC, October 4, 2021).

The emergence of the Delta variant, along with other VOCs, has resulted in a more deadly pandemic (Fisman and Tuite, July 12, 2021). While the Delta variant is the most transmissible SARS–CoV–2 variant to date, the possibility remains for the rise of future VOCs, and even more dangerous VOHCs, as the virus continues to spread and mutate. Inadequate vaccination rates and the abundance of transmission create an environment that can foster the development of new variants that could be similarly, or even more, disruptive (Liu and Rocklov, August, 4, 2021). In this context, it is critical that OSHA address the grave danger from COVID–19 that unvaccinated workers are currently facing by requiring vaccination and the other measures included in this rule, in order to significantly slow the transmission of COVID–19 in workers and workplaces and mitigate the rise of future variants.

b. Transmission

SARS–CoV–2 is a highly transmissible virus, regardless of variant. Since the first case was detected in the U.S., there have been close to 45 million reported cases of COVID–19, affecting every state and territory, with thousands more infected each day (CDC, October 18, 2021—Cumulative US Cases), and some indication that these numbers continue to underestimate the full burden of disease (CDC, July 27, 2021). According to the CDC, the primary way the SARS–CoV–2 virus spreads from an infected person to others is through the respiratory droplets that are produced when an infected person coughs, sneezes, sings, talks, or breathes (CDC, May 7, 2021). Infection could then occur when another person breathes in the virus. Most commonly this occurs when people are in close contact with one another in indoor spaces (within approximately six feet for at least fifteen minutes) (CDC, August 13, 2021). Additionally, airborne transmission may occur in indoor spaces without adequate ventilation where small respiratory particles are able to remain suspended in the air and accumulate (CDC, May 7, 2021; Fennelly, July 24, 2020). While scientists' understanding of the Delta variant's virology is evolving and remains at the frontier of science, current data shows that the routes of transmission remain the same for all currently-identified SARS–CoV–2 variants. In addition, all variants can be transmitted by people who are pre-symptomatic (*i.e.*, people who are infected but do not yet feel sick) or asymptomatic (*i.e.*, people who are infected but never feel any symptoms of COVID–19), as well as those who are symptomatic. Pre-symptomatic and asymptomatic transmission continue to pose serious challenges to containing the spread of COVID–19. For more extensive information on transmission routes, as well as pre-symptomatic and asymptomatic transmission, see the preamble to the Healthcare ETS (86 FR

32392–32396), which is hereby included in the record of this ETS.[7]

The Delta variant is transmitted from infectious individuals via the same routes as previous variants, but is much more transmissible. Specifically, Delta differs from previous dominant variants of SARS–CoV–2 in terms of the amplification of viral particles expelled from infected individuals. Testing of Delta-infected individuals indicates that their viral loads are—on average—approximately 1,000x greater than those of the SARS–CoV–2 variants from the first COVID–19 wave in early 2020. This finding suggests much faster replication of viral particles during early infection with the Delta variant, resulting in greater infectiousness (contagiousness) when compared to earlier versions of SARS–CoV–2 (Li et al., July 12, 2021).

The transmissibility of viruses is measured in part by the average number of subsequently-infected people (or secondary cases) that are expected to occur from each existing case (often referred to as R_0). Several comparisons of the transmissibility of the initial SARS–CoV–2 variants to the Delta variant have shown that Delta is approximately twice as transmissible (contagious) as previous versions of SARS–CoV–2 (CDC, August 26, 2021; Riou and Althaus, January 30, 2020; Li et al., July 12, 2021; Liu and Rocklov, August, 4, 2021), likely the result of higher initial viral loads during the pre-symptomatic phase (Li et al., July 12, 2021). In addition, as described further below, data on Delta shows that both unvaccinated and vaccinated individuals are more likely to transmit Delta than previous variants (Liu and Rocklov, August, 4, 2021; Eyre et al., September 29, 2021), making it especially dangerous to those who remain unvaccinated.

c. Health Effects

COVID–19 infections can lead to death. As reported in the Healthcare ETS, by May 24, 2021, there had been 587,432 deaths and 32,947,548 million infections in the U.S. alone (CDC, May 24, 2021a; CDC, May 24, 2021b). At that point in the pandemic, 1.8 out of every 1,000 people in the U.S. had died from COVID–19 (CDC, May 24, 2021a). Since then, reported cases have increased to 44,857,861 and the number of deaths has increased to 723,205 (CDC, October 18, 2021– Cumulative US Cases; Cumulative US Deaths). By September 2021, an astounding 1 in 500 Americans had died from COVID–19 (Keating, September 15, 2021). Updated mortality data[8] currently indicate that people of working age (18–64 years old) now have a 1 in 202 chance of dying when they contract the disease, with the risk much higher (1 in 72) for those aged 50–64 (CDC, October 18, 2021—Demographic Trends, Cases by Age Group; CDC, October 18, 2021—Demographic Trends, Deaths by Age Group). For a more in-depth description of the health effects resulting from SARS–CoV–2 infection, see the preamble to the Healthcare ETS (86 FR 32383–32392), which is hereby included in the record of this ETS.[9]

Apart from fatal cases, COVID–19 can cause serious illness, including long-lasting effects on health. Many patients who become ill with COVID–19 require hospitalization. Indeed, updated CDC hospitalization and mortality data indicate that working age Americans (18–64 years old) now have a 1 in 14 chance of hospitalization when infected with COVID–19 (CDC, October 18, 2021—Demographic Trends, Cases by Age; Total Hospitalizations, by Age). Those who are hospitalized frequently need supplemental oxygen and treatment for the disease's most common complications, which include pneumonia, respiratory failure, acute respiratory distress syndrome (ARDS), acute kidney injury, sepsis, myocardial injury, arrhythmias, and blood clots. One study, which included 35,502 inpatients nationwide, determined that the median length of hospital stay was 6 days, unless the cases required ICU treatment. For those cases, ICU stays were on median 5 days in addition to the time spent hospitalized outside of the ICU (Rosenthal et al., December 10, 2020). Another study that assessed hospital length of stay for COVID–19 patients in England estimated that a non-ICU hospital stay averaged between 8 and 9 days, but those estimates ranged from approximately 12 to 18 days when patients were admitted to the ICU (Vekaria et al., July 22, 2021). Moreover, given that SARS–CoV–2 is still a novel virus, the severity of long-term health effects—such as ''post-COVID conditions''—are not yet fully understood.

Many members of the workforce are at increased risk of death and severe disease from COVID–19 because of their age or pre-existing health conditions. The comorbidities that further exacerbate COVID–19 infections are common among adults of working age in the U.S. For instance, 46.1% of individuals with cancer are in the 20–64 year old age range (NCI, April 29, 2015), and over 40% of working age adults are obese (Hales et al., February 2020). Disease severity is also likely exacerbated by long-standing healthcare inequities experienced by members of many racial and economic demographics (CDC, April 19, 2021).

Recent data suggests that Delta variant infections may result in even more severe illness and a higher frequency of death than previous COVID–19 variants due to Delta's increased transmissibility, virulence, and immune escape (Fisman and Tuite, July 12, 2021). Symptomatic Delta variant infections do occur in fully vaccinated people (Mlcochova et al., June 22, 2021; Musser et al., July 22, 2021); however, as reported by the CDC (CDC, August 26, 2021), the vast majority of the continuing instances of severe and fatal COVID–19 infections are occurring in unvaccinated persons (discussed further in *Grave Danger*, Section III.A.IV. Vaccines Effectively Reduce Severe Outcomes from and Transmission of SARS–CoV–2). An assessment of Delta-related hospital admissions in Scotland found that hospitalizations were approximately doubled in patients with the Delta variant when compared to the Alpha variant (Sheikh et al., June 4, 2021). A similar study conducted using a retrospective cohort in Ontario, Canada compared the virulence of novel SARS–CoV–2 variants and found that the incidences of hospitalization, ICU admission, and death were more pronounced with the Delta variant than any other SARS–CoV–2 variant (Fisman and Tuite, July 12, 2021). A large national cohort study that included all Alpha and Delta SARS–CoV–2 patients in England between March 29 and May 23, 2021 found a ''higher hospital admission or emergency care attendance risk for patients with COVID–19 infected with the Delta variant compared with the Alpha variant,'' suggesting that Delta outbreaks—especially amongst unvaccinated populations—may lead to more severe health consequences and an equivalent or greater burden on healthcare services than the Alpha variant (Twohig et al., August 27, 2021). However, one more recent study examining data from several U.S. states demonstrated a significant increase in hospitalization from the pre-Delta to the Delta period, which may be related to increased transmissibility of Delta rather than

[7] This adoption includes the citations in the referenced section of the Healthcare ETS, which are also included in the docket for this ETS.

[8] Risk of death is based on averages from reported CDC data. Risks of hospitalization and death are much higher in unvaccinated individuals, as discussed further in *Grave Danger*, Section III.A.IV. Vaccines Effectively Reduce Severe Health Outcomes from and Transmission of SARS–CoV–2.

[9] This adoption includes the citations in the referenced section of the Healthcare ETS, which are also included in the docket for this ETS.

more severe health outcomes (Taylor et al., October 22, 2021).

III. Impact on the Workplace

SARS–CoV–2 is readily transmissible in workplaces because they are areas where multiple people come into contact with one another, often for extended periods of time. When employees report to their workplace, they may regularly come into contact with co-workers, the public, delivery people, patients, and any other people who enter the workplace. Workplace factors that exacerbate the risk of transmission of SARS–CoV–2 include working in indoor settings, working in poorly-ventilated areas, and spending hours in close proximity with others. Full-time employees typically spend 8 hours or more at work each shift, more time than they spend anywhere else but where they live. Employees work in proximity to others in workplaces that were not originally designed to keep people six feet away from other people and that may make it difficult for employees to perform work tasks while maintaining a six-foot distance from others. Even in the cases where workers can do most of their work from, for example, a private office within a workplace, they share common areas like hallways, restrooms, lunch rooms and meeting rooms. Furthermore, many work areas are poorly ventilated (Allen and Ibrahim, May 25, 2021; Lewis, March 30, 2021). An additional factor that exacerbates the risk of transmission of SARS–CoV–2 is interacting with or caring for people with suspected or confirmed COVID–19; this was a primary driver of OSHA's determination of grave danger for healthcare workers in the Healthcare ETS (see 86 FR 32381–32383). In recent weeks, the majority of states in the U.S. have experienced what CDC defines as ''high or substantial community transmission,'' indicating that there is a clear risk of the virus being introduced into and circulating in workplaces (CDC, October 18, 2021—Community Transmission Rates).

Although COVID–19 is not exclusively an occupational disease, it is evident from research accrued since the beginning of the pandemic that SARS–CoV–2 transmission can and does occur in workplaces, affecting employees and their lives, health, and livelihoods. This continues to be true for the Delta variant, with its increased transmissibility and potentially more severe health effects. This section describes some of the clusters, outbreaks, and other occurrences of workplace COVID–19 cases that government agencies, researchers, and journalists have described, and the widespread effects of SARS–CoV–2 in industry sectors across the national economy. While the focus is on more recent data reflecting the impact of the Delta variant, evidence of workplace transmission that occurred prior to the emergence of the Delta variant is also presented.

The workplace-based clusters described below provide evidence that workplaces in a wide range of industries have been affected by COVID–19, that many employees face exposure to infected people in their workspaces, and that SARS–CoV–2 transmission is occurring in the workplace, including during the recent period where the Delta variant has predominated. Although the presence of a cluster on its own does not necessarily establish that the cluster is work-related (*i.e.*, a result of transmission at the worksite), many state investigation reports and published studies provide evidence that transmission is work related by documenting that infections at a workplace occurred within 14-days (the incubation period for the virus) of each other and ruling out the possibility that transmission occurred outside the workplace. In addition, the information below demonstrates that exposures to SARS–CoV–2 happen regularly in a wide variety of different types of workplaces.

The basis for OSHA's grave danger finding is that employees can be exposed to the virus in almost any work setting; that exposure to SARS–CoV–2 can lead to infection (CDC, September 21, 2021); and that infection in turn can cause death or serious impairment of health, especially in those who are unvaccinated (see Section III.A.IV. *Vaccines Effectively Reduce Severe Health Outcomes from and Transmission of SARS–CoV–2*). The information described in this section supports OSHA's finding that employees who work in spaces shared by others are at risk of exposure to SARS–CoV–2. The degree of risk from droplet-based transmission may vary based on the duration of close proximity to a person infected with SARS–CoV–2, including the Delta variant, but the simple and brief act of sneezing, coughing, talking, or even breathing can significantly increase the risk of transmission if controls are not in place. SARS–CoV–2, including the Delta variant, might also be spread through airborne particles under certain conditions, particularly in enclosed settings with inadequate ventilation, which are common characteristics of some workplaces.

The peer-reviewed scientific journal articles, government reports, and news articles described below establish the widespread prevalence of COVID–19 among employees, beginning with a description of the recent impact from the Delta variant. OSHA's findings are based primarily on the evidence from peer-reviewed scientific journal articles and government reports. However, peer review for scientific journal articles and the assembly of information for government reports and other official sources of information take time, and therefore those sources do not always reflect the most up-to-date information (Chan et al., December 14, 2010). In addition, while state and local health departments can report workplace outbreaks to CDC, the agency does not provide summary statistics by workplace so that those outbreaks can be tracked on a national level. In the context of the COVID–19 pandemic, given the recent impacts due to the Delta variant and the emergence of new information on a daily basis, it is critical for OSHA to rely on the most up-to-date information available. Therefore, OSHA has occasionally supplemented peer-reviewed data and government reports with additional information on occupational outbreaks contained in other sources of media (*e.g.*, newspapers, digital media, and information submitted to or obtained by private organizations).[10] The reported information from other sources can provide further evidence of the impact of an emerging and changing disease, especially for industries that are not well represented in the peer-reviewed scientific literature. Together, these sources of information represent the best available evidence of the impact on employees of the pandemic thus far.

The information described herein illustrates a significant number of infections among employees in a variety of industries, with virtually every state continuing to experience what CDC defines as high or substantial community transmission related to the recent surge of the Delta variant. The industries and types of workplaces described are not the only ones in which a grave danger exists. The science of transmission does not vary by industry or by type of workplace. OSHA therefore expects transmission to occur in diverse workplaces all across the country (see *Dry Color Mfrs. Ass'n, Inc.* v. *Dep't of Labor*, 486 F.2d 98, 102 n.3 (3d Cir. 1973) (holding that when OSHA determines a substance poses a grave

[10] OSHA did not make findings based solely on non-peer-reviewed sources such as news articles, but the agency found that those sources can sometimes provide useful information when considered with more robust sources.

danger to workers, OSHA can assume an exposure to a grave danger exists wherever that substance is present in a workplace)). In addition, the severity of COVID–19 does not depend on where an employee is infected; an employee exposed to SARS–CoV–2 might die whether exposed while working at a meat packing facility, a retail establishment, or an office (see *Grave Danger*, Section III.A.V.b. Employees Who Work Exclusively Outside, below, for a discussion of the risk of exposure in outdoor workplaces).

a. General Impact on Workers

Data on SARS–CoV–2 infections, illnesses, and deaths among employees in general industry, agriculture, construction, and maritime support OSHA's finding that COVID–19 poses a grave danger to employees in these sectors across the U.S. economy. This section summarizes studies and reports of COVID–19 illness and fatalities in a wide range of workplaces across those industry sectors. Not all workplace settings are discussed; nor is the data available to do so. However, the characteristics of the various affected workplaces—such as indoor work settings; contact with coworkers, clients, or members of the public; and sharing space with others for prolonged periods of time—indicate that exposures to SARS–CoV–2 are occurring in a wide variety of work settings across all industries. Therefore, most employees who work in the presence of other people (*e.g.*, co-workers, customers, visitors) need to be protected.

While there is no comprehensive source of nationwide workplace infection data, reports from states and communities on outbreaks related to workplaces provide key, up-to-date data that illustrate the likelihood of employee exposure to SARS–CoV–2 at workplaces throughout the U.S. OSHA identified a number of recent reports from various regions of the country that together demonstrate the impact that SARS–CoV–2 can have on a variety of workplaces, including in service industries (*e.g.*, restaurants, grocery and other retail stores, fitness centers, hospitality, casinos, salons), corrections, warehousing, childcare, schools, offices, homeless shelters, transportation, mail/shipping/delivery services, cleaning services, emergency services/response, waste management, construction, agriculture, food packaging/processing, and healthcare. Deaths are reported in many studies performed prior to the emergence of the Delta variant but, because the Delta outbreak is so recent and deaths can occur weeks after infection, the number of deaths from recent infections might be underestimated. Some of the reports include cumulative data representing various phases of the pandemic, beginning prior to the availability of vaccines and continuing through the recent surge of the Delta variant. In addition, some studies report investigations of recent outbreaks, which provide insight on the impact of the Delta variant as well as impacts associated with the current vaccination status of workers.

The Washington State Department of Health (WSDH) reports outbreaks occurring in non-healthcare workplaces (WSDH, September 8, 2021). In non-healthcare workplaces, outbreaks are defined as two or more laboratory confirmed cases of COVID–19, with at least two cases reporting symptom onset within 14 days of each other, and plausible epidemiological evidence of transmission in a shared location other than a household. As of September 4, 2021, WSDH reported 5,247 outbreaks in approximately 40 different types of non-healthcare work settings. During the week of August 29 through September 4, 2021, WSDH identified 137 separate workplace outbreaks. The types of non-medical workplace settings that represented more than 5% of the total outbreaks during that week included food service/restaurants, childcare, schools, retail, grocery, and shelter/homeless services. Other types of non-healthcare settings where outbreaks occurred recently included non-food and food manufacturing, construction, professional services/office based, agriculture/produce packing, transportation/shipping delivery, government agencies/facilities, leisure hospitality/recreation, corrections, utilities, warehousing, facility/domestic cleaning services, youth sports/activities, camps, and public safety. Over the course of the pandemic, outbreaks have also been observed at bars/nightclubs, hotels, and fishing/commercial seafood vessels.

The Oregon Health Authority (OHA) publishes a weekly report detailing outbreaks directly related to work settings. OHA epidemiologists consider cases to be part of a workplace outbreak when clusters form with respect to space and time, within a plausible incubation period for the virus, and their investigation does not uncover an alternative source for the outbreak. For privacy reasons, OHA only reports outbreaks with 5 or more cases in workplaces with 30 or more people. OHA reported a total of 26,013 cases and 135 deaths related to workplace outbreaks as of September 1, 2021. As of September 1, 2021, OHA was investigating more than 124 active workplace outbreaks (OHA, September 1, 2021). Those outbreaks occurred in a wide variety of industries including correctional facilities, emergency services, waste management, schools and child care, retail and grocery stores, restaurants, warehousing, agriculture, food processing/packaging, construction, healthcare, mail and delivery services, office locations, utilities, transportation, and others.

Tennessee Department of Health was investigating 557 active COVID–19 clusters as of September 8, 2021 (TDH, September 8, 2021). Clusters are defined as two or more laboratory confirmed COVID–19 cases linked to the same location or event that is not a household exposure. The clusters occurred in 13 types of settings, 10 of which were workplace settings. Outbreaks at workplaces represented more than half of the total active outbreaks in the state at that time. Settings comprising more than 5% of total clusters included assisted care living facilities, nursing homes, and correctional facilities. Other types of workplaces where outbreaks occurred included bars, construction, farms, homeless shelters, and industrial settings.

The North Carolina Department of Health and Human Services reports cumulative numbers of clusters, cases, and deaths for workers in poultry processing facilities (beginning in April of 2020) and other types of workplaces (beginning in May of 2020) (NCDHHS, August 30, 2021). Clusters are defined as a minimum of 5 cases with illness onset or initial positive results within a 14-day period and plausible epidemiological linkage between the cases. Plausible epidemiological linkage means that multiple cases were in the same general setting during the same time period (*e.g.*, same shift, same physical area) and that a more likely source of exposure is not identified (*e.g.*, household contact or close contact to a confirmed case in another setting). During that time period of April/May 2020 through August 30, 2021, workplaces [11] were associated with nearly 80% of the 1,969 clusters and 27,097 cases observed and nearly 40% of the 167 deaths related to the clusters. Cumulative numbers of cluster-associated deaths were highest in meat and poultry processing (25 of 5,351 cases), followed by healthcare (10 of 1,036 cases), government services and manufacturing (5 of 1,048 cases and 5 of

[11] NCDHHS identifies a ''workplace'' category in their report (*e.g.*, agriculture, construction), but OSHA includes other settings where employees would be present (*e.g.*, retail, restaurants, childcare, healthcare).

1,856 cases, respectively), and restaurants and childcare (3 of 421 cases and 3 of 1,943 cases, respectively). Recently, in July of 2021, the number of cases associated with workplace clusters began increasing in several different types of work settings, including meat processing, manufacturing, retail, restaurants, childcare, schools, and higher education.

Colorado Department of Public Health & Environment/Colorado State Emergency Operations Center (CDPHE/CSEOC, September 8, 2021) reported 5,584 resolved workplace-related outbreaks involving 40,156 employee cases and 79 employee deaths since May of 2020. The agency's current investigations, as of September 8, 2021 included 291 active outbreaks (not defined), with 2,865 staff cases (assumed to be cases in employees). The majority of active outbreaks were reported in childcare, schools, healthcare, and corrections. Active outbreaks were also reported in construction, retail, homeless shelters, casinos, restaurants, hotels, offices, law enforcement, manufacturing, delivery services, and warehouses. Other types of work settings that were affected in resolved outbreaks included warehouses, bars, government locations, waste management, utilities, salons, emergency services, meat processing/packaging, and postal services. From June 21, 2021 (the date the healthcare ETS was published) through September 8, 2021, 1,469 staff cases associated with outbreaks were reported, for an average of approximately 19 cases per day.

Similar reporting is available from Louisiana's Department of Health (LDH, August 24, 2021), with 1,347 outbreaks and 9,130 cases reported as of August 24, 2021. LDH defines an outbreak as 2 or more cases among unrelated individuals who visited a site within a 14-day period. More than three quarters of outbreaks through that date were associated with workplaces. Workplace settings in Louisiana that experienced more than 5% of outbreaks included day care facilities, bars, restaurants, retail settings, industrial settings, and office spaces. Other types of workplace settings or industries where outbreaks occurred included casinos, gyms/fitness centers, banks, automotive services, construction, and ships/boats.

In addition to the state data above, some published studies and government reports provide information on recent workplaces outbreaks. For example, 47 people, including 3 of 11 staff members, 23 gymnasts, and 21 household contacts, contracted COVID–19 from an outbreak linked to an Oklahoma gymnastics facility during April 15 through May 3, 2021 (Dougherty et al., July 16, 2021). All 21 of the virus samples sequenced were determined to be the Delta variant. The majority of the infected individuals (85%) were unvaccinated. Infections were reported in 16 adults aged 20 years or older; two adults were hospitalized and one required intensive care.

The state of Hawaii defines clusters as three or more confirmed or probable cases linked to a site or event within 14 days, with no outside exposure of cases to each other (Hawaii State, August 19, 2021). The state reported a COVID–19 cluster in July associated with a concert at a bar that affected 16 people, including employees, band members, and concert attendees; infections also spread to 7 household members. Band members had performed while sick. Four of the initial 16 people and none of the household members who tested positive for COVID–19 were fully vaccinated. The concert cluster was linked to clusters at another workplace and another concert. The report lists additional clusters investigated in the two weeks prior to the report; those clusters were observed in workplace locations such as correctional facilities, bars and nightclubs, restaurants, construction/industrial sites, travel/lodging/tourism, schools, food suppliers, and gyms.

Additional evidence that employees are at risk of exposure to SARS–CoV–2 in the workplace is available from published, peer-reviewed studies that were conducted before the Delta variant emerged. Those studies demonstrate that employees have been at risk of infection, illness, and death throughout the COVID–19 pandemic. Because the Delta variant is more transmissible and likely causes more severe disease than previous variants, there is even greater potential for unvaccinated employees to become seriously ill or die as a result of exposure to the Delta variant.

Contreras et al. (July, 2021) examined workplace outbreaks (excluding healthcare settings, homelessness services, and emergency medical services) in Los Angeles county from March 19 through September 30, 2020. Workplace outbreaks were defined as 5 or more suspected or laboratory confirmed COVID–19 cases (prior to May 29) or 3 or more laboratory confirmed cases (after May 29) occurring within 14 days. Nearly 60% of the 698 identified outbreaks occurred in three sectors—manufacturing (184, 26.4%), retail trade (137, 19.6%), and transportation and warehousing (73, 10.5%). Also notable were the 71 outbreaks in the accommodation and food services industry, which represented 10.2% of the outbreaks. The study authors concluded that outbreaks were larger and lasted longer at facilities with more onsite staff.

Outbreaks in Wisconsin from March 4 through November 16, 2020 were also examined (Pray et al., January 29, 2021). Non-household outbreaks were defined as two or more confirmed COVID–19 cases that occurred within 14 days in persons who attended the same facility or event and did not share a household. During the period from March 4 through November 16, 2020, the largest percentages of cases were associated with outbreaks in long-term care facilities (26.8% of cases), correctional facilities (14.9% of cases), and colleges or universities (15% of cases). Also notable were the substantial number of cases associated with outbreaks in food production or manufacturing facilities (including meat processing and warehousing; 14.5% of cases) and schools and childcare facilities (10.6% of cases).

Bui et al. (August 17, 2020) analyzed data from the Utah Department of Health's COVID–19 case surveillance system, which included data on workplace outbreaks. Outbreaks were defined as two or more laboratory confirmed cases occurring within a 14 day period among coworkers in a common workplace (*e.g.*, same facility). During the time period between March 6 and June 5, 2020, 277 COVID–19 outbreaks were reported, of which 210 (76%) occurred in workplaces. The 210 workplace outbreaks occurred in 15 of 20 industry sectors, and the industry sectors of manufacturing (43 outbreaks, 20%), construction (32 outbreaks, 15%), and wholesale trade (29 outbreaks, 14%) together represented nearly half of workplace outbreaks. Other sectors that represented more than 10% of total outbreaks were retail trade (28 outbreaks, 13%) and accommodation and food services (25 outbreaks, 12%). Incidence rates of COVID–19 over the period of March 6 through June 5, 2020 were 339/100,000 workers in manufacturing, 122/100,000 workers in construction, 377/100,000 workers in wholesale trade, 68/100,000 workers for retail trade, and 78/100,000 workers for accommodation and food services. For COVID–19 cases associated with workplace outbreaks in which hospitalization and severity status were known (1,382 and 1,155, respectively), the number in all sectors who were admitted to the hospital was 85 (6%) and the number with severe outcomes (intensive care unit admission, mechanical ventilation, or death) was 40 (3%).

The impact of SARS–CoV–2 exposures on employee infection, illness, and death has also been demonstrated in studies focusing on specific types of industries, such as those where employees have frequent contact with each other and the public (*e.g.*, grocery stores, bars, fitness facilities, schools, and law enforcement/corrections). For example, a study by Lan et al. (September 26, 2020) demonstrates the risk of infection in service industries. The cross-sectional study examined the risks of SARS–CoV–2 exposure and infection for employees in a Boston, Massachusetts-area retail grocery store market. The study tested 104 grocery store employees, of whom 20% (21 employees) were positive for COVID–19; 76% of confirmed cases did not have symptoms. After adjusting for gender, smoking, age, and the prevalence of COVID–19 in the employees' residential communities, employees who had direct customer exposure (*e.g.*, cashiers, sales associates, cart attendants) were 5.1 times more likely to have a positive test for COVID–19 than employees without direct face-to-face customer exposure (*e.g.*, stockers, backroom, receiving and maintenance). The infection rate of 20% among all employees was significantly higher than the rate in the surrounding community.

In February of 2021, an event at an Illinois bar that accommodates approximately 100 people resulted in a COVID–19 outbreak that affected 46 people, including 3 (10%) staff members, 26 (90%) patrons, and 17 secondary cases (Sami et al., April 9, 2021). People at the event included an asymptomatic person diagnosed with COVID–19 on the previous day and 4 symptomatic people who were later diagnosed with COVID–19. The outbreak resulted in a school closure and the hospitalization of a resident at a long-term care facility.

In Minnesota, 47 COVID–19 outbreaks were detected at fitness facilities from August through November of 2020 (Suhs et al., July 23, 2021). One outbreak at a fitness facility during October through November of 2020 resulted in 23 COVID–19 cases including 5 (22%) employees and 18 (78%) members. A genetic analysis of specimens from 3 employees and 10 members identified 2 distinct genetic subclusters, indicating two distinct chains of transmission among members and employees.

School-related outbreaks were examined from December 1, 2020 through January 22, 2021 in eight public elementary schools of a Georgia school district (Gold et al., February 26, 2021). A COVID–19 case was determined to be school-related if (1) symptom onset or a positive test was consistent with the incubation period of the virus following contact with an index case or a school-associated case, (2) close contact occurred with the index case or school-associated case while that person was infected, and (3) no known contact occurred with an infected community or household contact in the two weeks prior to a positive test for COVID–19. The investigators identified nine clusters of three or more epidemiologically linked COVID–19 cases that involved 13 educators and 32 students in six of the eight elementary schools. Approximately half of the school-associated cases involved two clusters that began with probable transmission between educators, followed by educator to student transmission. Eighteen of 69 household members tested received positive results.

A number of studies demonstrate the impact of COVID–19 in law enforcement and related fields such as corrections. For example, a study examining COVID–19 antibodies in employees from public service agencies in the New York City area from May through July of 2020, found that 22.5% of participants had COVID–19 antibodies (Sami et al., March, 2021). The percentage of correctional officers found to have COVID–19 antibodies (39.2%) was the highest observed among all the occupations. The percentages of police dispatchers, traffic officers, security guards, and dispatchers found to have COVID–19 antibodies (29.8 to 37.3%) were among the highest levels observed in all the occupations. The study authors noted that those jobs involve frequent or close contact with the public or are done in places where employees work in close proximity to their coworkers.

Wallace et al. (May 15, 2020) evaluated data on COVID–19 cases and deaths among correctional facility employees and inmates from January 21 to April 21, 2020. Data were reported to CDC by 37 (69%) of 54 state and territorial health department jurisdictions. Of these 37 jurisdictions, 32 (86%) reported at least one COVID–19 case from a correctional facility. Of the 420 facilities with a case, 221 (53%) reported cases only among staff members. In total, 4,893 COVID–19 cases among incarcerated or detained persons and 2,778 cases among staff members were reported (total tested not provided). Among staff member cases, 79 hospitalizations (3%) and 15 deaths (1%) were reported. The study authors noted that ''correctional and detention facilities face challenges in controlling the spread of infectious diseases because of crowded, shared environments and potential introductions by staff members and new intakes.''

Ward et al. (June 2021) analyzed COVID–19 prevalence among prisoners and staff in 45 states from March 31, 2020 through November 4, 2020. During that time period, COVID–19 cases in staff were 3 to 5 times higher compared to the U.S. population. Average daily increases in cases were 42 per 100,000 prison employees, 61 per 100,000 prisoners, and 13 per 100,000 U.S. residents. On November 4, 2020, COVID–19 prevalence for prison staff was 9,316 cases per 100,000 employees, which was 3.2 times greater than prevalence in the U.S. population (2,900 cases per 100,000).

Kirbiyik et al. (November 6, 2020) analyzed movement through a network-informed approach to identify likely high points of transmission within the Cook County Jail in Chicago, IL. At that facility, over 900 COVID–19 cases were reported across 10 housing divisions in 13 buildings from March 1–April 30, 2020. Staff members were required to report symptoms of COVID–19 (probable cases) or receipt of a positive test result (confirmed cases). A total of 2,041 staff members (77% of staff) were included in the network analysis because information was available about their shift and division assignments, and 198 (9.7%) of those staff members had COVID–19 during the two-month study period. Connections between staff members who had COVID–19 were higher than expected, suggesting likely transmission among staff members. Fewer connections than expected were observed among detained persons with SARS–CoV–2 infections, suggesting the effectiveness of medical isolation at reducing transmission.

The Officer Down Memorial Page, which tracks police officer fatalities determined to be occupationally related, reported that the majority of officer deaths for 2021 (157 of 269) were related to COVID–19 (ODMP, September 14, 2021). For the 269 officers who died, causes of death were not reported for each month, but the highest numbers of monthly deaths, 52 in January and 65 in August (compared to 16 to 34 deaths on other reported months), were consistent with the winter surge of COVID–19 and, more recently, the surge caused by the Delta variant.

The risk of COVID–19 has also been examined in industries where employees have little contact with the public, such as construction, and food processing, and where most exposure to

SARS–CoV–2 likely comes from other workers. Pasco et al. (October 29, 2020) examined the association between construction work during the COVID–19 pandemic and community transmission and construction worker hospitalization rates in Austin, Texas from March 13 to August 20, 2020. A ''Stay Home-Work Safe'' order enacted on March 24, 2020, limited construction to only critical infrastructure and excluded commercial and residential work. One week later, the Texas governor lifted the restriction for essential workers and allowed all types of construction work to resume, while keeping the order in place for other workers. The authors found that resuming construction during the shelter-in-place order led to an increase in community transmission, an increase in hospitalizations among community members, and an increase in hospitalizations of construction workers. By mid-July, Austin Public Health identified at least 42 clusters (not defined) of COVID–19 cases in the construction industry; 515 individuals were hospitalized for COVID–19 illnesses acquired as part of these clusters, and 77 of those reported working in construction. The study found that construction workers had a nearly 5-fold increased risk of hospitalization in central Texas compared with workers in other occupations. The authors' model predicted that allowing unrestricted construction work would be associated with an increase in COVID–19 hospitalization rates from 0.38 per 1,000 residents to 1.5 per 1,000 residents overall, and from 0.22 per 1,000 construction workers to 9.3 per 1,000 construction workers for the construction industry specifically. The authors concluded that stringent workplace safety measures could significantly mitigate risks related to COVID–19 in the industry.

The meat packing and processing industries and related agricultural and food processing sectors have also been impacted by COVID–19. Waltenburg et al. (January, 2021) reported COVID–19 cases in employees from meat and poultry processing facilities in 31 states from March 1 through May 31, 2020. As reported in Table 2 of that report, 28,364 employees in those facilities were confirmed to have COVID–19 by laboratory testing and 132 died. Among the 20 states that reported total numbers of employees, 11.4% of the workers were diagnosed with COVID–19 (with a range of 3.1 to 27.7% of workers in individual states). For states that reported at least one COVID–19-related death, the percentages of employees who died in each state ranged from 0.1 to 2.4% of those with COVID–19. The authors found a high burden of disease in persons employed at these facilities who were racial or ethnic minorities. Higher incidence in these populations might be due to the likelihood of these employees working in areas in the plant where transmission risk is higher. Steinberg et al. (August 7, 2020) reported that attack rates (i.e., the number of individuals who are infected in comparison to the total number at risk) among production employees in the Cut (30.2%), Conversion (30.1%), and Harvest (29.4%) departments of a meat processing plant (where spacing between employees is less than 6 feet) were double that of salaried employees (14.8%) whose workstations had been modified to increase physical distancing from others.

Waltenburg et al. (January, 2021) also evaluated COVID–19 incidence in food manufacturing and agricultural settings (*e.g.*, manufacturing or farming involving fruits, vegetables, dairy, baked goods, eggs, prepared foods), as reported in 30 states from March through May 2020. In food manufacturing and farming of fruits, vegetables, dairy, and other items, 742 workplaces were affected, including 8,978 infections and 55 fatalities. For states that reported total numbers of employees, the proportion of employees who developed COVID–19 in each state ranged from 2.0 to 43.5%. For states that reported at least one death, the percentages of deaths among cases ranged from 0.1 to 3.8%.

Porter et al. (April 30, 2021) reported that 13 COVID–19 outbreaks occurred at Alaska seafood processing facilities and vessels (both of which were described as high density workplaces) during the Summer and early Fall of 2020. The 13 outbreaks involved 539 COVID–19 cases, with 2–168 cases per outbreak. Attack rates in facilities and offshore vessels ranged from less than 5% to 75%. Outbreaks were also reported in entry quarantine groups. Because of these outbreaks, it was determined that vaccination of these essential workers is important and requirements for COVID–19 prevention were updated to include smaller quarantine groups, serial testing, and testing before transfers from one facility or vessel to another.

Finally, two published studies analyzed death records to determine how mortality rates among individuals in various types of workplaces had changed during the pandemic. Chen et al. (June 4, 2021) analyzed records of deaths occurring on or after January 1, 2016 in California and found that mortality rates in working aged adults (18–65 years) increased 22% during the COVID–19 pandemic period of March through November 2020 compared to pre-pandemic periods. Relative to pre-pandemic periods, the groups of employees experiencing the highest, statistically significant increases in relative excess mortality were those in food/agriculture (39% increase), transportation/logistics (31% increase), facilities (23% increase), and manufacturing (24% increase). Other groups that also experienced excess, statistically significant mortality compared to pre-pandemic periods were health or emergency workers (17% increase), retail workers (21% increase), and government and community workers (17% increase). The study authors concluded that certain occupational sectors were impacted disproportionally by mortality during the pandemic and that essential work conducted in-person is a likely avenue of infection transmission.

Hawkins et al. (January 10, 2021) examined death certificates of individuals who died in Massachusetts between March 1 and July 31, 2020. An age-adjusted mortality rate of 16.4 per 100,000 employees was determined from 555 death certificates that had useable occupation information. Employees in 11 occupational groups had particularly high mortality rates: healthcare support; transportation and material moving; food preparation and serving; building and grounds cleaning and maintenance; production, construction and extraction; installation/maintenance/repair; protective services; personal care services; arts/design/entertainment; sports/media; and community and social services. The study authors noted that occupational groups expected to have frequent contact with sick people, close contact with the public, and jobs that are not practical to do from home had particularly elevated mortality rates.

b. Healthcare Workers

As explained in the Healthcare ETS, COVID–19 presents a grave danger to workers in all U.S. healthcare settings where people with COVID–19 are reasonably expected to be present (86 FR 32381). Healthcare settings covered by the Healthcare ETS primarily include settings where people with suspected or confirmed COVID–19 are treated, exacerbating the risk present in most workplaces. To control the higher level of risk in those settings, OSHA determined that a suite of workplace controls was necessary to protect all employees, whether they are vaccinated or unvaccinated. As explained further

below, OSHA now finds that unvaccinated healthcare workers in healthcare settings not covered by the Healthcare ETS are also at grave danger from exposure to SARS–CoV–2, just like unvaccinated workers in other industries. Data continue to be collected and reported for healthcare workers, and a small number of peer-reviewed studies demonstrate the potential impact of the Delta variant on healthcare workers.

CDC continues to provide updates for COVID–19 cases and deaths among healthcare personnel. However, information on healthcare personnel status continues to be reported for only a fraction (18.91%) of total reported cases, and death status was reported for only 82.16% of healthcare personnel cases as of October 18, 2021 (CDC, October 18, 2021—Healthcare Personnel). Given incomplete reporting, the data from this source represent only a fraction of actual healthcare cases and deaths. Nevertheless, CDC reported 666,707 healthcare personnel cases among the 6,754,306 reported cases that included information on healthcare personnel status (9.9%) and 2,229 fatalities among the 547,769 cases that included death status (0.4%) for healthcare employees as of October 18, 2021. This is a 26% increase in the number of cases and a 27% increase in the number of deaths since the May 24, 2021 data reported in the ETS (CDC, October 18, 2021—Healthcare Personnel). The Delta variant is likely responsible for the majority of those deaths. No healthcare worker deaths were reported by CDC during the weeks of May 30 through June 13, 2021; however, as the Delta variant's prevalence rose after June 20, healthcare worker deaths began increasing; they peaked during the period of August 15 through September 12, 2021, when 34 to 36 healthcare worker deaths were reported per week (CDC October 18, 2021—Healthcare Personnel, Deaths by Week). Independent reporting by Kaiser Health News and The Guardian reported more than 3,600 fatalities in health care workers as of April 2021 (Spencer and Jewett, April 8, 2021). That number is expected to be higher at this time since the earlier figure did not include the most recent 5 months of the pandemic, which includes the period of Delta variant predominance.

Published studies also demonstrate that healthcare workers, especially those who are unvaccinated, remain at risk of being infected with SARS–CoV–2 (see Section III.A.IV. Vaccines Effectively Reduce Severe Health Outcomes from and Transmission of SARS–CoV–2). Routine testing of health care personnel, first responders, and other frontline workers in eight U.S. locations in six states from December 14, 2020 through August 14, 2021 revealed 194 infections in 4,136 unvaccinated participants (89.7% symptomatic) and 34 infections in 2,976 fully vaccinated participants (80.6% symptomatic) (Fowlkes et al., August 27, 2021). During time periods when the Delta variant represented more than 50% of viruses sequenced, 19 infections were detected in 488 unvaccinated participants (94.7% symptomatic) and 24 infections were detected in 2,352 vaccinated participants (75% symptomatic).

Monthly COVID–19 cases in healthcare workers were reported during the period from March 1 to July 31, 2021 at the University of California San Diego (UCSD) health system, which is a healthcare provider that includes primary care services such as family medicine and pediatrics (Keehner et al., September 1, 2021; UCSD, 2021). During that time period, a total of 227 health care workers tested positive for COVID–19. One hundred and nine of 130 fully vaccinated workers who tested positive (83.8%) were symptomatic and 80 of 90 unvaccinated workers (88.9%) were symptomatic; one unvaccinated person was hospitalized for COVID–19 symptoms. By July of 2021, after the end of California's mask mandate on June 15 and after the Delta variant became dominant, the number of cases detected dramatically increased; the Delta variant accounted for more than 95% of SARS–CoV–2 viruses sequenced by the end of that month. During July of 2021, symptomatic infections were detected in 94 of 16,492 fully vaccinated workers and 31 of 1,895 unvaccinated workers. Attack rates in July of 2021 were 5.7 per 1,000 fully vaccinated workers and 16.4 per 1,000 unvaccinated workers.

In Finland, a Delta variant infection from a hospitalized patient spread throughout the hospital and to three primary care facilities, infecting 103 individuals, including 45 healthcare workers (Hetemäki et al., July 29, 2021). Twenty-six of the healthcare workers were infected at the hospital and 19 were infected at primary care facilities. The affected health care workers included 28 with direct patient contact (11 who were not fully vaccinated), 8 unvaccinated healthcare worker students, and 9 other staff, including hospital cleaners and secretaries (of whom 6 were not fully vaccinated). According to study authors, ''There was high vaccine coverage among permanent staff in the central hospital, but lower for HCW in primary healthcare facilities. . .'' Study authors estimated that vaccine effectiveness against the Delta variant in healthcare workers was approximately 88–91%, suggesting how much more extensive the outbreak could have been if a high percentage of healthcare workers were not fully vaccinated.

In the UK, a Delta variant infection in a healthcare worker resulted in an outbreak in a care home that affected 16 of 21 residents and 8 of 21 staff (Williams et al., July 8, 2021). One staff member was hospitalized. Attack rates were 35.7% in staff who were partially vaccinated (*i.e.*, received their second dose of vaccine on the day that the index case was diagnosed with COVID–19 or had only received one vaccine dose) and 40% in staff who were not vaccinated.

Recent news stories demonstrate that outbreaks affecting staff members are still occurring in U.S. healthcare facilities. An outbreak that began in August, 2021 at a Washington State nursing center resulted in infections in 22 staff members and 52 residents. In an unrelated outbreak, a nursing facility in Hawaii reported infections in 24 employees and 54 patients (Wingate, September 24, 2021). Vaccination rates were reported at 64.5% of residents and 37.1% of staff in the Washington State facility and 91% of staff and more than 80% of patients at the Hawaii facility.

COVID–19 cases were also observed in staff at ambulatory care settings prior to emergence of the Delta variant. Over an 11-week period beginning on March 20, 2020, 254 tests for SARS–CoV–2 were performed on employees who had potential exposures at an outpatient urology center in New York State (Kapoor et al., 2020). Positive test rates in employees correlated with rates in New York State, declining over time, from 26.1% in the early stage to 7.3% in the late stage of the study. According to study authors, the positive test results coincided with the implementation of infection control procedures (*e.g.*, symptom screening, masking, distancing, and hygiene). Positivity rates were similar in administrative and clinical staff and the study authors concluded that ''administrative staff in an outpatient setting were equally—if not more—vulnerable to SARS–CoV–2 transmission when compared with clinical staff who were more directly exposed to patients.'' The study authors speculated that possible reasons for the findings were that clinical staff were more familiar with PPE and that administrative staff, especially in check-in and check-out points, tend to work close to each other.

c. Conclusion for Employee Impact

The evidence described above provides examples of the impact that exposures from SARS–CoV–2, including those involving the Delta variant, have had on employees in general industry, agriculture, construction, maritime, and healthcare settings. It demonstrates that SARS–CoV–2 has spread to employees in these industries and, in many cases, infection was linked to exposure to infected persons at the worksite (WSDH, September 8, 2021; OHA, September 1, 2021; TDH, September 8, 2021; NCDHHS, August 30, 2021; Hawaii State, August 19, 2021; Pray et al., January 29, 2021; Sami et al., April 9, 2021; Suhs et al., July 23, 2021; Gold et al., February 26, 2021; Porter et al., April 30, 2021; Hetemäki et al., July 29, 2021; Williams et al., July 8, 2021). The documentation of so many workplace clusters suggests that exposures to SARS–CoV–2 occur regularly in workplaces where employees come into contact with others. This prevalence of clusters, combined with some evidence that many infections occurred within the 14-day incubation period for SARS–CoV–2 and that exposures to infected persons outside the workplace were frequently ruled out, supports the proposition that exposures to and transmission of SARS–CoV–2 occur frequently at work. Multiple studies demonstrate high rates of COVID infections, illnesses, and fatalities in the wide range of occupations that require frequent or prolonged close contact with other people, indoor work, and work in crowded and/or poorly ventilated areas The large numbers of infected employees suggest that SARS–CoV–2 is likely to be present in a wide variety of workplaces, placing unvaccinated workers at risk of serious and potentially fatal health effects.

IV. Vaccines Effectively Reduce Severe Health Outcomes From and Transmission of SARS–CoV–2

During the course of the SARS–CoV–2 pandemic, different variants have emerged with different characteristics that better enable transmission and potentially cause more severe outcomes. However, vaccines remain very effective at reducing the occurrence of COVID–19-related severe illness, disability and death.[12] The Delta variant is more transmissible than previous variants, might cause more severe illness than previous variants in unvaccinated people, and has led to hospitalization of individuals in numbers similar to those of the November 2020 to February 2021 surge. These changes in characteristics have provided a clearer realization of the continuing capacity for SARS–CoV–2 to present a grave danger to workers. However, it is well evident that even given these changed characteristics of Delta, serious disease and death continue to occur overwhelmingly in unvaccinated individuals while the vaccinated are afforded great protection.[13]

a. Impact of Vaccination on Severe Health Outcomes

There are currently three vaccines that are approved or authorized for the prevention of COVID–19 in the U.S.: The Pfizer-BioNTech COVID–19 vaccine (FDA approved for ages 16 and above; authorized for ages 12 and above), the FDA-authorized Moderna COVID–19 vaccine (authorized for ages 18 and above), and the FDA-authorized Janssen COVID–19 vaccine (also known as the Johnson & Johnson vaccine; authorized for ages 18 and above.) Pfizer-BioNTech and Moderna are mRNA vaccines that require two primary series doses administered three weeks and one month apart, respectively. Janssen is a viral vector vaccine administered as a single primary vaccination dose (CDC, September 15, 2021). The vaccines were shown to greatly exceed minimum efficacy thresholds in preventing COVID–19 in clinical trial participants (FDA, December 11, 2020; FDA, December 18, 2020; FDA, February 26, 2021). Data from clinical trials for all three vaccines and observational studies for the two mRNA vaccines clearly establish that fully vaccinated persons have a greatly reduced risk of SARS–CoV–2 infection compared to unvaccinated individuals. This includes severe infections requiring hospitalization and those resulting in death. For more information about the effectiveness of vaccines as of late Spring 2021, see 86 FR 32397, which OSHA hereby includes in the record for this ETS.[14]

Vaccines remain highly effective against hospitalization and death. A study evaluating vaccine effectiveness at preventing hospitalization among those with SARS–CoV–2 infections in New York found that effectiveness did not change from May 3 to July 25, 2021 as the Alpha variant gave way to the Delta variant (91.9–96.2% range; Rosenberg et al., August 27, 2021). Grannis et al. used data from 187 hospitals in nine states from June to August 2021 to evaluate the efficacy of vaccines against hospitalization when Delta had emerged as the predominant variant causing SARS–CoV–2 infections (September 17, 2021). This study found that vaccines were 89% effective at preventing hospitalization in individuals aged 18 to 74. Similarly, vaccines were also found to be 89% effective in preventing hospitalization in a study collecting data from five Veteran Affairs Medical Centers from July 1 to August 6, 2021, a time when most transmission was attributed to the Delta variant (Bajema et al., September 10, 2021).

Two other studies found that, although the level of protection provided by vaccination has decreased somewhat with the emergence of the Delta variant, vaccines continue to provide high levels of protection against hospitalization. In a U.S. study, researchers found that while the Moderna and Janssen vaccines mostly maintained their effectiveness at preventing hospitalization (going from 93% to 92% after more than 120 days post-vaccination and 71% to 68% after more than 28 days post-vaccination, respectively) from March to August 2021, the effectiveness of the Pfizer-BioNTech vaccine at preventing those severe outcomes decreased from 91% to 77% after more than 120 days post-vaccination (Self et al., September 17, 2021). An Israeli study on infections documented between July 11 and July 31, 2021 found a significant decrease in vaccine efficacy for the Pfizer-BioNTech vaccine against severe outcomes in relation to when an individual was vaccinated, but the absolute difference was much less than what was observed in the U.S. study (e.g., 98% effective for 40–59 year olds vaccinated in March versus 94% effective for those in the same age group who were vaccinated in January) (Goldberg et al., August 30, 2021).

Vaccines also remain extremely effective at preventing death. A UK study evaluated the effectiveness of the Pfizer-BioNTech vaccine against death and found it to be 96.3% effective against the Alpha strain and 95.2% protective against the Delta strain (Andrews et al., September 21, 2021). Two Israeli studies, Haas et al. and Saciuk et al., performed during time periods where Alpha was predominant, found the Pfizer-BioNTech vaccine to be 96.7% and 91.1% effective,

[12] A discussion of vaccination rates, as well as OSHA's rationale for why vaccination is a critical means of protecting workers from the grave danger described in this section, can be found in Need for the ETS (Section III.B. of this preamble).

[13] While mild cases of COVID–19 are included in the grave danger presented by COVID–19, as stated in the Healthcare ETS (see 86 FR 32382), OSHA is focusing on the most severe health effects, i.e., cases requiring hospitalization and cases resulting in death, in this new rulemaking effort in order to prevent the gravest of consequences to workers.

[14] This adoption includes the citations in the referenced section of the Healthcare ETS, which are also included in the docket for this ETS.

respectively, against death (Haas et al., May 15, 2021; Saciuk et al., June 25, 2021). A California study found that the Moderna vaccine was 97.9% effective against death (Bruxvoort et al., September 2, 2021). A study on patients served by the Veterans Health Administration found that Pfizer-BioNTech and Moderna vaccines provided 99% effectiveness against death (Young-Xu et al., July 14, 2021).

The risks of hospitalization and death appear to have increased for unvaccinated individuals since the Delta variant became a common source of infections. A study of Los Angeles County SARS–CoV–2 infections found that vaccinations reduced hospitalization risk by a factor of 10 on May 1, 2021, when the Alpha variant was dominant, but that the risk of hospitalization was even more greatly reduced (by a factor of 29.2) on July 25, 2021, when the Delta variant was dominant (Griffin et al., August 27, 2021). This difference suggests both that vaccines continue to provide a high level of protection against disease that results in hospitalization and that risk has increased for those who are unvaccinated. Similar increased risk for unvaccinated individuals was reported in a study that evaluated hospitalization and death data from 13 U.S. jurisdictions between June 20 and July 17, 2021, a period when the Delta variant gained prominence (Scobie et al., September 17, 2021). For unvaccinated 18 to 49 year olds, the risk of hospitalization was 15.2 times greater, and the risk of death was 17.2 times greater, than the risks for vaccinated people in the same age range. For unvaccinated 50 to 64 year olds, the risk of hospitalization was 10.9 times greater, and the risk of death was 17.9 times greater, than for those who are vaccinated. These studies illustrate that vaccination is an extremely effective control measure to minimize severe outcomes resulting from Delta variant infections.

b. Impact of Vaccination on Infection and Transmission

Vaccines continue to provide robust protection for vaccinated individuals against SARS–CoV–2 infections, even though several studies indicate that vaccine efficacy against infection may have decreased somewhat with the emergence of the Delta variant (Fowlkes et al., August 27, 2021; Rosenberg et al., August 27, 2021; Nanduri et al., August 27, 2021; Seppala et al., September 2, 2021; Bernal et al., August 12, 2021). For example, vaccination was observed to reduce the risk of infection by a factor of 8.4 on May 1, 2021, when the Alpha variant was predominant in Los Angeles county (Griffin et al., August 27, 2021). However, the level of protection had fallen to a factor of 4.9 by July 25, 2021, when Delta made up 88% of infections in the county. The findings from this study indicate that while vaccines maintain robust protection against severe outcomes, protection against infection has fallen with the increased circulation of the Delta variant. A broader study using data from 13 U.S. jurisdictions had similar findings, observing that the protection vaccines afforded against infection decreased from a factor of 11.1 (*i.e.*, vaccinated people were 11.1 times less likely than unvaccinated people to become infected) between April 4 and June 19, 2021, to a factor of 4.6 between June 20 and July 17, 2021 (Scobie et al., September 17, 2021). An additional study noted, however, that the decrease in vaccine protectiveness against symptomatic infection from the Delta variant could be due to the waning of immunity specifically in older populations. Andrews et al. (September 21, 2021) found that while the Pfizer-BioNTech vaccine effectiveness decreased from 94.1% to 67.4% in those 65 years old and older, vaccine effectiveness for those 40 to 64 years old only decreased from 92.9% to 80.6%.

While infections themselves do not normally result in serious illness for those who are vaccinated, evidence shows that vaccinated individuals who become infected with the Delta variant can transmit the disease more easily to others than with previous variants. This development poses a great concern for the unvaccinated, who generally do not have the protections against severe outcomes that vaccination affords. Before Delta, vaccinated individuals were shown to have lower estimated viral loads when infected than those who were unvaccinated, which suggested that infected vaccinated individuals were likely not a major concern for transmission (Levine-Tiefenbrun et al., March 29, 2021). Transmission studies prior to the emergence of Delta appear to bear this out. A Scottish study performed during a time period when the Alpha variant was predominant in the region, showed that a fully vaccinated individual was 3.2 times less likely than an unvaccinated individual to transmit the virus to unvaccinated family members (Shah et al., September 10, 2021; supplementary appendix). A population-based study from the Netherlands found that vaccination decreased secondary transmission to household members from 31% to 11% (de Gier et al., August 5, 2021). Additionally, a study from the UK found that household transmission decreased by as much as 50% when the infected individual was vaccinated (Harris et al., June 23, 2021).

More recent research suggests that the Delta variant may have reduced the level of protection vaccination affords against transmission of the virus to others, but still significantly reduces transmission risk in comparison to infected unvaccinated individuals. A UK study found that fully vaccinated individuals infected by the Delta variant are able to transmit the virus to both vaccinated and, to a greater degree, unvaccinated persons (Singanayagam et al., September 6, 2021). Still, the rate at which transmission to unvaccinated individuals occurred was nearly double the rate of transmission to vaccinated individuals (35.7% compared to 19.7%). Similarly, Eyre et al., (September 29, 2021) found that during the predominance of Alpha, full vaccination with the Pfizer-BioNTech vaccines resulted in a significant reduction in transmission to others (an adjusted Odds Ratio (aOR) of 0.18, meaning that being unvaccinated increased the odds of transmission by over five times). With the rise of the Delta variant, that reduction in transmission to others was less than with the Alpha variant, but still significantly more than for unvaccinated individuals (aOR of 0.35, meaning that being unvaccinated increased the odds of transmission by almost three times).

The greater ability for vaccinated individuals to transmit the Delta variant of SARS–CoV–2 to others (compared to previous variants) appears to be linked to the generation of similar viral loads (as estimated by Ct threshold) in the vaccinated compared to the unvaccinated (Ct threshold is the number of RT–PCR cycles that need to be run in order to amplify the RNA enough to be detected—fewer cycles means a greater initial amount of virus was collected) (Singanayagam et al., September 6, 2021). This observation has been made in several studies. A study from Israel observed that viral loads among those infected with the Delta variant were only decreased in people who had been vaccinated recently (within the past two months) or in those who had recently received a booster dose (Levine-Tiefenbrun et al., September 1, 2021). In a study of SARS–CoV–2 infections in Los Angeles County, performed when the Delta variant was predominant, vaccination status did not appear to affect the estimated viral loads, suggesting that infected individuals who are vaccinated

may be just as likely to transmit the virus (Griffin et al., August 27, 2021). Additionally, estimated viral loads did not appear to be significantly different with respect to vaccination status in a Wisconsin study (Riemersma et al., July 31, 2021). Regardless of viral loads in vaccinated and unvaccinated individuals, the fact remains clear that unvaccinated people pose a higher risk of transmission to others than vaccinated people, simply because they are much more likely to get COVID–19 in the first place.

These studies, however, appear to overstate increases in transmission risk from vaccinated individuals related to the Delta variant. From May to July 2021, UK researchers tested individuals at random to better characterize viral load estimates in people with asymptomatic as well as symptomatic infections; they found that vaccination was associated with a significantly lower estimated viral load (Elliott et al., September 10, 2021). This more comprehensive study (*i.e.*, Elliott et al., September 10, 2021) may have been able to better characterize the course of infection and to incorporate vaccinated individuals whose viral loads were decreasing quickly. The findings in Elliott et al. are consistent with studies observing that viral load may fall more quickly in vaccinated individuals, resulting in a shorter infectious period and possibly fewer transmission events (Chia et al., July 31, 2021; Eyre et al., September 29, 2021).

c. Conclusion for the Impact of Vaccines

The studies discussed above indicate that vaccines continue to effectively protect vaccinated individuals against SARS–CoV–2 infections, while the risk of infection, hospitalization, and death increased among unvaccinated people as the Delta variant became predominant in the U.S. The Delta variant is even more dangerous to unvaccinated individuals than previous variants because of the higher transmission potential from both unvaccinated and vaccinated people. Because unvaccinated individuals are at much higher risk of severe health outcomes from infection with SARS–CoV–2, and also pose a greater transmission risk to those around them, it is critical to assure that as many people as possible are fully vaccinated in order to prevent transmission at work.

V. Coverage of OSHA's Grave Danger Finding

Based on the information discussed above, OSHA finds that many unvaccinated workers across the U.S. economy are facing a grave danger of severe health effects or death from exposure to SARS–CoV–2. Fully vaccinated workers are not included in this grave danger finding because, as described throughout this section, those who are fully vaccinated are much better protected from the effects of SARS–CoV–2 and, in particular, the most severe effects, than are those who are unvaccinated.[15] Beyond that, OSHA's grave danger determination exempts several categories of workers based on characteristics of their work or workplace: (1) Workers who do not report to a workplace where other individuals are present or who telework from home; and (2) workers who perform their work exclusively outdoors. The basis for these exemptions is explained below. In this section, OSHA also addresses the basis for OSHA's grave danger finding for workers who are unvaccinated yet had a prior COVID–19 infection, and explains the Agency's more nuanced grave danger finding in the healthcare industry.

a. Employees Who Telework and Employees Who Do Not Report to a Workplace Where Other People Are Present.

Employees who report to workplaces where no other people are present face no grave danger from occupational exposure to COVID–19 because such exposure requires the presence of other people. For those who work from their homes, or from workplaces where no other people are present (such as a remote worksite), the chances of being exposed to SARS–CoV–2 through a work activity are negligible. Therefore, OSHA is exempting those workers who do not come into contact with others for work purposes from its grave danger finding as well as the scope of the ETS (for more information, see the Summary and Explanation for Scope and Application, Section VI.B. of this preamble).

b. Employees Who Work Exclusively Outside

Employees who work exclusively outside face a much lower risk of exposure to SARS–CoV–2 at work, because their workplaces typically do not include any of the characteristics that normally enable transmission to occur (*e.g.*, indoors, lack of ventilation, crowding). Bulfone et al. attributed the lower risk of transmission in outdoor settings (*i.e.*, open air or structures with one wall) to increased ventilation with fresh air and a greater ability to maintain physical distancing (November 29, 2020). While the best available evidence firmly establishes a grave danger in indoor settings, the CDC has stated that the risk of outdoor transmission is ''low'' (CDC, September 1, 2021) and OSHA is unable to establish a grave danger in outdoor settings from exposure during normal work activities.

OSHA recognizes that outdoor transmission has been identified in a few specific incidents (*e.g.*, 2 of 7,324 cases, Qian et al., October 27, 2020). However, general reviews of transmission studies that include large-scale and high-density outdoor gatherings indicate that indoor transmission overwhelmingly is responsible for SARS–CoV–2 transmission. Additionally, the lack of evidence tied to specific case studies illustrating outdoor transmission in comparison to the bevy of case studies on indoor transmission makes it difficult to support a conclusion that outdoor transmission rises to the level of a grave danger.

Bulfone et al. reviewed a collection of SARS–CoV–2 studies that evaluated infections in outdoor and indoor settings (November 29, 2020), and found that transmission is significantly less likely to occur in outdoor settings than in indoor settings. The studies overall found that the risk of outdoor transmission was less than 10% of the risk of transmission in indoor settings, with three of the studies concluding risk was 5% or less of the risk of transmission in indoor settings. While acknowledging significant gaps in knowledge, the authors of a different study suggested that increases in transmission related to large events such as the Sturgis motorcycle rally may be related to lack of local efforts to prevent transmission indoors (e.g., requiring the wearing of masks, closing indoor dining), rather than the outdoor setting for the rally (Dave et al., December 2, 2020). In contrast, transmission rates did not increase as expected following the Summer 2020 protests on racial injustice. This outcome was attributed, in part, to participants having been less likely to enter indoor commercial establishments.

[15] The exclusion of vaccinated workers from this grave danger finding does not mean that vaccinated workers face no risk from exposure to SARS–CoV–2. The best available evidence clearly shows that vaccination provides great protection from infection and severe outcomes, but breakthrough infections do occur and vaccinated individuals can still transmit the virus to others. In some cases, the level of risk to vaccinated workers may even rise to the level of a significant risk, the standard OSHA must meet for promulgation of a permanent standard under section 6(b)(5) of the OSH Act (29 U.S.C. 655(b)(5)).

Weed and Foad (September 10, 2020) found that transmission of SARS–CoV–2 related to large scale outdoor gatherings could be largely attributed to individual behaviors related to that event, such as communal travel and indoor congregation at other facilities (*e.g.*, restaurants, shared accommodations), rather than to the time spent outdoors at those gatherings. Similarly, a Public Health England evaluation of the literature on SARS–CoV–2 and surrogate respiratory viruses (December 18, 2020) also concluded that when transmission does occur at outdoor events, outdoor activities were mixed with indoor setting use. Public Health England concluded that the vast majority of transmission happens in indoor settings, with very little evidence for outdoor transmission.

A systemic review of SARS–CoV–2 clusters identified 201 events through May 26, 2020 (Leclerc et al., April 28, 2021), only 4 of which occurred at predominantly outdoor settings. For those 4 clusters, the authors noted that they were not able to evaluate specific transmission events and attributed it to local health agencies being overwhelmed by the pandemic. OSHA notes that the designations of settings in this study are somewhat generic, as outdoor construction sites will often have indoor locations, such as mobile offices, or locations with reduced airflow, such as areas with a roof or ceiling and two or more walls. Regardless, this study illustrates the comparable abundance of evidence available to evaluate SARS–CoV–2 transmission in indoor settings versus outdoor settings.

Cevik et al. (August 1, 2021) reviewed studies on the transmission dynamics of SARS–CoV–2 infections from large scale, contact-tracing studies. The authors recommended that, based on the evidence that outdoor transmission dynamics resulted in significantly fewer infections than in indoor settings, public health entities should greatly encourage use of outdoor settings. The researchers highlighted a study by Nishiura et al. (April 16, 2020), who evaluated 110 cases in Japan at the beginning of the pandemic and found that outdoor settings reduced transmission risk by 18.7 times and reduced the risk of super-spreader events by 32.5 times.

Agricultural workplace settings have experienced significant SARS–CoV–2 infections. However, transmission in these settings is difficult to characterize because many jobs in this sector include both outdoor and indoor activities. Miller et al. (April 30, 2021) evaluated an outbreak among farmworkers in Washington State. The researchers found that 28% of workers with predominantly indoor tasks where they were unable to maintain physical distance were infected, compared to 6% of workers who performed predominantly outdoors tasks in the orchards. Conversely, a study on farmworkers in Monterey County, California found a significant correlation between evidence of infection and individuals who worked in the fields as opposed to indoor work (Mora et al., September 15, 2021). The paper noted that infections were predominant in individuals who lived in crowded conditions, commuted together to the fields, and spoke at home in indigenous languages, which is important as written health messages are often not available in all worker languages. These papers cannot identify where or when infections occurred in order to discern causation. The associations observed may indicate that SARS–CoV–2 infections may be more related to aspects related to indoor exposures outside of the work activities (*e.g.*, crowded living conditions) or potentially overlooked indoor aspects connected to outdoor work (*e.g.*, shared commuting).

Several studies discussed below in more detail have evaluated outdoors on-field transmission from infected participants during football, soccer, and rugby matches. These events include repeated close physical contact between players, without PPE or physical distancing, over the course of fairly long events, with increased exertion leading to greater respiratory effort and production of respiratory droplets. These events also include opposing cohorts who only interact during on-field activities. Therefore, these studies provide some evidence for the low likelihood of outdoor transmission in other workplace activities greatly impacted by the pandemic, such as in construction.

Mack et al. (January 29, 2021) detailed the National Football League's complex program to assess and prevent transmission, which included devices that recorded distance and duration of interactions with others, for the purpose of improving identification of individuals with high-risk exposures. Although 329 positive cases were identified among roughly 11,400 players and staff, there were no reported cases of on-field transmission by infected players. The results led the NFL to focus more on reducing transmission in indoor settings, including transportation.

Egger et al. (March 18, 2021) reviewed three soccer matches involving 18 players who had SARS–CoV–2; one match involved a team where 44% of the players were infected. Video analysis was used to determine the type of contact between players, such as contact to face or hand slaps. None of the existing cases were associated with on-field play and no secondary transmission from on-the-field contacts was observed. Jones et al. (February 11, 2021), evaluated four rugby Super League matches involving eight players who were found to be infected with SARS–CoV–2. Using video footage and global positioning data, the researchers were able to identify 28 players as high-risk contacts with the infected players. These high-risk players together had as many as 32 tackles and were within two meters of infected players as often as 121 times during the four matches. Of the 28 players noted as high-risk contacts, one became infected with SARS–CoV–2. However, researchers determined that the transmission resulted from internal team outbreaks and not from exposure on the field.

OSHA acknowledges that the risk of transmission of SARS–CoV–2 in outdoor settings is not zero, and that there may be some low risk to workers performing general tasks exclusively in outdoor settings. However, where studies have been able to differentiate between indoor and outdoor exposures, they indicate that indoor exposures are the much more significant drivers of SARS–CoV–2 infections. Therefore, the best available evidence at this time does not provide OSHA with the information needed to establish SARS–CoV–2 as a grave danger for general work activities in outdoor settings (see Int'l Union, United Auto., Aerospace, & Agr. Implement Workers of Am., UAW, 590 F. Supp. at 755–56, describing a ''grave danger'' as a risk that is more than ''significant''). Therefore, OSHA has excluded employees who work exclusively outdoors from the scope of this ETS (see the Summary and Explanation for Scope and Application, Section VI.B. of this preamble).

c. Employees in Healthcare

Because OSHA issued a separate grave danger determination several months ago for some healthcare workers, some explanation of how its current finding applies to healthcare workers is necessary. In June 2021, OSHA issued its Healthcare ETS (86 FR 32376) after determining that some healthcare workers faced a grave danger of infection from SARS–CoV–2. This grave danger determination, along with the protections of the Healthcare ETS, applied to healthcare and healthcare support workers in settings where

people with suspected or confirmed cases of COVID–19 are treated, and was based on the increased potential for transmission of the virus in such settings (see 86 FR 32411–32412). These workers are currently covered by the protections of the Healthcare ETS (29 CFR 1910.502). OSHA does not have data to demonstrate that unvaccinated workers in settings covered by the Healthcare ETS face a grave danger from SARS–CoV–2 when the requirements of that standard are followed. However, if the Healthcare ETS were no longer in effect, OSHA would consider the workers who were covered by it, and who remain unvaccinated, to be at grave danger for the reasons described in this ETS.

OSHA's new finding of grave danger applies to healthcare and healthcare support workers who are not covered by the Healthcare ETS, to the extent they remain unvaccinated. In this ETS, as discussed in this section, OSHA has made a broader determination of grave danger that applies to most unvaccinated workers, regardless of industry. OSHA's current finding of grave danger supporting this ETS does not depend on whether a workplace is one where people with suspected or confirmed COVID–19 are expected to be present. Therefore, the finding of grave danger applies to unvaccinated workers in healthcare settings that are not covered by 29 CFR 1910.502 to the same extent it applies to unvaccinated workers in all other industry sectors.

d. Employees Who Were Previously Infected With SARS–CoV–2

OSHA has carefully evaluated the effectiveness of previous SARS–CoV–2 infections in providing protection against reinfection. This section provides a detailed description of the current scientific information in order to ascertain what the best available scientific evidence on this topic indicates regarding the risk to individuals with previous COVID–19 infections from exposure to SARS–CoV–2. While the agency acknowledges that the science is evolving, OSHA finds that there is insufficient evidence to allow the agency to consider infection-acquired immunity to allay the grave danger of exposure to, and reinfection from, SARS–CoV–2.

To determine whether employees with infection-induced immunity from SARS–CoV–2 (*i.e.*, those who were infected with SARS–CoV–2 but have not been vaccinated) face a grave danger, OSHA reviewed the scientific evidence on the protective effects of vaccine-induced SARS–CoV–2 immunity versus infection-induced immunity. Individual immunity to any infectious disease, including SARS–CoV–2, is achieved through a complex response to exposure by the immune system. This response consists of disease-specific antibody production guided and augmented by certain types of immune cells, such as T and B cells, which work together to neutralize or destroy the disease-causing agent. Immune responses to viruses like SARS–CoV–2 can be measured in several ways. For instance, blood serum can be taken and exposed to specific proteins found on the SARS–CoV–2 virus, in order to measure the presence of antibodies in the blood. Another antibody test, the neutralization test, measures the ability of the antibodies present in a serum to neutralize infectivity and prevent cells from being infected. T cell immunity can be measured using techniques that target a specific biomolecule that is specific to SARS–CoV–2.

A considerable number of individuals who were previously infected with SARS–CoV–2 do not appear to have acquired effective immunity to the virus (Psichogiou et al., September 13, 2021; Wei et al., July 5, 2021; Cavanaugh et al., August 13, 2021). The level of protection afforded by infection-induced immunity appears to depend on the severity of individuals' infections. In a study from Greece, immunogenicity was compared between healthcare workers who were vaccinated with Pfizer-BioNTech and unvaccinated patients who acquired a natural infection (Psichogiou et al., September 13, 2021). The researchers found that the immune response in unvaccinated individuals correlated to the severity of their disease. Fully vaccinated healthcare workers had immune responses (measured as antibody levels specific to SARS–CoV–2) that were 1.3 times greater than patients who had critical cases of COVID–19 cases, 2.5 times greater than patients who had moderate to severe cases, and 10.5 times greater than patients who had asymptomatic/mild illnesses. Similarly, another study found that 24.0% (1,742 of 7,256) of individuals who had a previous SARS–CoV–2 infection were seronegative (*i.e.*, did not produce antibodies in response to the virus), suggesting that the previous infection provided insufficient protection against future infection (Wei et al., July 5, 2021). Individuals who were seronegative were typically older, had lower viral burdens when infected, and were more likely to be asymptomatic. The authors posited that the immunity of those who were seropositive (*i.e.,* did produce antibodies in response to the virus) would provide some measure of protection, but that these individuals would benefit from a vaccination booster. This position appears to be validated by a study that compared the reinfection rates of individuals in Kentucky based on their post-recovery vaccination status (Cavanaugh et al., August 13, 2021). Unvaccinated individuals with previous infection were found to be 2.3 times more likely to be reinfected than those who were vaccinated after their prior infection. These studies demonstrate not only that those with milder infections may not be protected against future infection, but that it is difficult to tell, on an individual level, which individuals might have had prior infections that conveyed protection equivalent to that provided by vaccination.

A number of other studies indicate that fully vaccinated individuals may be better protected against future infection than those with previous infections. A study in Massachusetts concluded that the immunity conveyed from a previous SARS–CoV–2 infection was effectively equivalent to the immunity of an uninfected individual who has had only one dose of an mRNA vaccine (Naranbhai et al., October 13, 2021). The authors found that fully vaccinated individuals have an immune response (*i.e.,* antibodies and neutralization) well above the levels observed in unvaccinated, previously-infected individuals. German researchers found that individuals who were fully vaccinated with Pfizer-BioNTech had a significantly greater immune response (as measured by antibody levels) than unvaccinated individuals who had infections, concluding that vaccination would be needed for those unvaccinated individuals to have similar protection against infection (Herzberg et al., June 13, 2021). Similarly, a Dutch study observed that vaccination greatly improved the immune response (as measured by antibodies and virus-specific T cells) of individuals who had recovered from COVID–19 (Geers et al., May 25, 2021). Planas et al. (August 12, 2021) also noted that immune response (as measured by neutralization) to the Alpha, Beta, and Delta (B.1.617.2) variants in unvaccinated, previously-infected individuals was considerably less than the immune response in individuals five weeks after their second Pfizer-BioNTech dose. When unvaccinated, previously-infected individuals were vaccinated, their immune response (as measured by neutralization) increased by more than an order of magnitude. Likewise, Wang

et al. (July 15, 2021) found that the immune response (as measured by neutralization) of those with previous SARS–CoV–2 infection increased by more than an order of magnitude against Alpha (B.1.1.7), Beta (B.1.351), Iota (B.1.526), and Gamma (P.1) variants when they were vaccinated. These studies show that infection-induced immunity may not equal the protection afforded by vaccination and that vaccination greatly improves the immune response of those who were previously infected.

The aforementioned studies indicate that immunity acquired through infection appears to be less protective than vaccination. There are also a number of epidemiological studies that provide some evidence that infection-acquired immunity has the potential to provide a significant level of protection against reinfection. As OSHA discusses in greater detail below, these studies suffer from methodological limitations that render them inconclusive about the level of immunity conferred by infection, and therefore OSHA is unable to establish that such immunity eliminates grave danger. This determination is based in three parts.

First, the epidemiological literature OSHA reviewed generally suffers from selection bias to a degree that it serves as an unreliable basis on which to reach a robust conclusion on whether previous infection removes workers from grave danger. In general, the studies described below do not account for people who had mild COVID–19 infections, leading to study findings regarding the level of protection afforded by prior infection that are not generally applicable. Second, the tests employed in the studies are being used in ways that they were not originally designed to be employed. These tests are powerful tools, but there are limitations to their use in determining if a specific individual is, in fact, protected from the grave danger of SARS–CoV–2. Particularly problematic is the lack of established thresholds to determine full protection from reinfection or even a standardized methodology to determine infection severity or immune response. Thus, while these studies broadly establish some increase in protectiveness against SARS–CoV–2 among the studied populations, they as yet are unable to provide a reasonable degree of certainty on whether the degree of protection afforded any particular individual from their prior infection is sufficient to eliminate the grave danger from reinfection (see Milne, et al., October 21, 2021.) Third, while the research methodology itself creates difficulties in the context of OSHA's grave danger inquiry, the implications of trying to apply investigative research methodology to clinical practice are even more challenging. The need for the development of standardized methods and criteria for establishing sufficient immunity preclude the application of the studies' findings to robust and reliable clinical practice. These three rationales for OSHA's finding are described in more detail below.

Several epidemiological studies used previous RT–PCR positive cases to define previous infections (Hansen et al., March 27, 2021; Pilz et al., February 11, 2021; Vitale et al., May 28, 2021; Pouwels et al., October 14, 2021; Braeye et al., September 15, 2021; Hall et al., April 17, 2021). RT–PCR tests, particularly in the beginning of the pandemic, were given high priority to discern who seeking medical care was, in fact, infected. For instance, the progression of testing from medical needs to more of a community perspective is illustrated in Denmark (Vrangbaek et al., April 29, 2021). Denmark, considered one of the gold standard countries for its comprehensive testing program, missed five infections for every one it identified in the spring of 2020 (Espenhaim et al., August 22, 2021). Hansen et al. (March 27, 2021) depended greatly on these first surge infection definitions to determine that survivors had protection of 80.5% effectiveness during the second surge in Denmark from September through December, 2020. By only noting RT–PCR positives from the spring when testing was limited and highly focused on health care needs, it seems apparent that the study excluded many less severe cases (which are less likely to result in an effective immune response against reinfection), leading to results that may suggest greater protection is afforded by infection than in actuality. Even by December of 2020, it appears Denmark's gold standard comprehensive testing approach was only able to capture roughly half of all infections. Similar systemic undercounts have also been determined to be true in the United States where approximately three out of four infections have never been reported (CDC, July 27, 2021b).

It is important to recognize that RT–PCR testing was not implemented to find every infection, but was used instead to assist in determining when medical and community interventions were necessary. Infections without symptoms or with mild symptoms likely would not require medical intervention and, therefore, would likely not be identified via testing. The absence of this population that is more vulnerable to reinfection, in these studies, undercuts their usefulness in OSHA's grave danger analysis, because they may overestimate the protectiveness of immunity acquired through infection.

Several other studies in regions less known for their sampling approach than Denmark also were heavily dependent on early, limited pandemic RT–PCR testing. An Austrian study found a roughly ten-fold decrease in reinfection in survivors of reported infections from February to April 30, 2020 in comparison with the general public (Pilz et al., February 11, 2021). The authors noted that ''infections in the first wave are likely to have been far more common than the documented ones'' and referred to their results as a ''rough estimate.'' Researchers at the Cleveland Clinic also found a reduced rate of reinfection in those who had a reported previous infection compared with those with no prior infection (13.8% infection rate for those previously uninfected and 4.9% infection rate for those previously infected), but noted that testing was limited in that the ''Cleveland Clinic did not test asymptomatic patients unless they were admitted to hospital or undergoing a procedure/surgery'' (Sheehan et al., March 15, 2021). These criteria for testing create uncertainty in determining the level of effectiveness previous infection provides against SARS–CoV–2 because many individuals with asymptomatic infections would not have been tested. Similar issues are also found in studies on populations in Italy, Belgium, and the UK (Vitale et al., May 28, 2021; Braeye et al., September 15, 2021; Pouwels et al., October 14, 2021).

To avoid the well-known problems with RT–PCRs defining previous infection, other studies have defined previous infection as testing positive for antibodies specific for SARS–CoV–2 (Lumley et al., February 11, 2021; Abu-Raddad et al., April 28, 2021; Hall et al., April 17, 2021). As noted above, previous infection does not necessarily result in a seropositive outcome; one study indicated that nearly a quarter (24%) of those infected with SARS–CoV–2 subsequently showed no sign of an immune response in SARS–CoV–2-specific antibody testing (Wei et al., July 5, 2021). Therefore, studies only considering seropositive individuals are in essence studying only the individuals most likely to have protection from reinfection. Lumley et al. (February 11, 2021) found that those having a seropositive response had almost an order of magnitude fewer infections (e.g., 0.11 adjusted incidence rate ratio). Likewise, Abu-Raddad et al. (April 28,

2021) found that seropositive individuals were reinfected less (0.7%) during their study period in comparison to seronegative individuals (3.09%). In addition to the bias associated with using antibodies to determine previous infection, the authors also noted that there may have been issues with being able to document cases with mild or no symptoms.

Hall et al. (April 17, 2021) cast a wider net by defining previous infection to include both positive RT–PCR tests and seropositivity. The researchers found that those who were considered previously infected had an 84% lower risk of infection compared to those who were unvaccinated with no record of infection. While the study does attempt to capture as many previously-infected individuals as possible, this does not actually address the weaknesses of each method. Those with less severe infections were less likely to have sought out or been able to get an RT–PCR test during the first surge, which is when an overwhelming number of the previous infections were recorded in this study (March through May, 2020). Additionally, the less severe infections that are most likely underrepresented in the study appear to be the ones that are less likely to produce seropositivity. Shenai et al. (September 21, 2021) pooled several studies with the above issues and concluded that immunity acquired through a previous infection from SARS–CoV–2 may be as protective as, or more protective than, the immunity afforded by vaccination to an individual without previous infection. However, authors of several of those underlying studies used in the analysis noted that their studies were limited by not having the capability to fully account for asymptomatic infections (the aforementioned Lumley et al., July 3, 2021; Gazit et al., August 25, 2021; Shrestha et al., June 19, 2021). As noted earlier, infection severity appears to be correlated with the robustness of immunity acquired through that infection, so the failure to account for asymptomatic infections may mean that this finding is related to the protection afforded by more severe disease. While pooled analyses can be utilized to make powerful observations, those observations are highly dependent upon the underlying studies not sharing the same methodological weakness which, in this case, was the studies' exclusion of asymptomatic infections.

Moreover, while the evidence suggests that severe infection may provide significant protection against reinfection in some cases (Milne et al., October 21, 2021), the level of protection cannot be determined on an individual basis. The studies discussed above are based on tests that show only whether a person was or was not infected and provide no information about the severity of the infection. Because the studies are likely biased towards those who had a relatively serious infection, their findings cannot be generalized to all individuals with prior infections.

RT–PCR and antibody testing are powerful tools with many clinical and research applications. However, the application of these tools cannot determine what degree of protection a particular individual has against SARS–CoV–2 without a great deal of additional study concerning thresholds establishing individual immunity. Therefore, these tools are not yet able to assist OSHA in making more nuanced findings about which workers who had COVID–19 previously are at grave danger. There is no established threshold to determine full protection from reinfection or a standardized methodology to determine infection severity or immune response. Studies use Ct threshold to approximate viral loads and infer disease severity, but that metric depends on many variables (e.g. time of collection during infection, quality of collection, handling of sample, specifics of the test protocol and materials, precision in performing the protocol) that are often of far less importance when it is used as a crude diagnostic to determine the presence of an infection. In other words, it is reasonable to say that the lower the Ct count, the greater the likelihood that an individual is at a lower reinfection risk; however, the Ct count is greatly dependent on the RT–PCR test used, and how different laboratories may run that test, which cannot be discerned. Similarly, research needs to be done to better identify the minimum protective threshold of anti-SARS–CoV–2 serum neutralizing antibodies (Milne et al., October 21, 2021). Thus, these studies currently do not allow OSHA to determine, with a reasonable degree of certainty, how much protection employees with prior infections have against reinfection.

Furthermore, while the research methodology itself raises challenges in making the grave danger determination, the implications of trying to apply investigative research methodology to clinical practice are even more difficult. The lack of standardized methods and standardized measures for immunity preclude their application to robust and reliable clinical practice. One major drawback discussed above is that, in contrast to vaccine studies where researchers know who was vaccinated with a standardized dosing regime, scientific inquiries likely will not be able to identify most individuals who were infected, the degree of disease experienced for those with a confirmed infection, and the immunity against reinfection. As of October 18, 2021, several RT–PCR assays have been authorized without standardization or assessment with respect to measuring disease severity (FDA, October 18, 2021). As noted above, the use of the Ct threshold to approximate viral loads and infer disease severity is unreliable. As the FDA notes, the same is true about antibody tests, which are considered to be poor indicators for individuals to use to determine whether they are protected from reinfection (FDA, May 19, 2021). There are many different SARS–CoV–2-specific antibody tests that focus on different specificity. Not only are the outcomes of these tests not directly comparable to each other, but the specificity of these tests is not related to any notion of protection against reinfection. It can be reasonably said that a greater antibody response means a greater likelihood of protection against infection, but, again, the science is not clear what those thresholds are and whether a threshold would be comparable between laboratories. At this point in time, even if OSHA determined that some individuals with prior infections are not at grave danger from exposure to SARS–CoV–2, there is no agreement on what indicators of infection might be sufficient to confer this level of immunity or how a healthcare provider or employer could document that a certain level of immunity had been achieved.

Based on the best available evidence described above, OSHA concludes that while some individuals who were infected with SARS–CoV–2 may have significant protection from subsequent infections, the level of protection afforded by infection may be significantly impacted by the severity of the infection and some previously infected individuals may have no future protection at all. In addition, given the limitations of the studies described above, there is considerable uncertainty as to whether any given individual is adequately protected against reinfection. Furthermore, the level of protection, if any, provided by a given person's SARS–CoV–2 infection cannot be ascertained based on currently-available testing methods. Therefore, OSHA finds that the requirements of this ETS are necessary to protect unvaccinated individuals who had prior SARS–CoV–2 infections from the grave danger from exposure to SARS–CoV–2.

OSHA recognizes that its finding regarding infection-induced immunity is being made in an area of inquiry that is currently on the ''frontiers of scientific knowledge'' (*Indus. Union Dep't, AFL–CIO* v. *Am. Petroleum Inst.*, 448 U.S. 607, 656 (1980)). For these reasons, OSHA finds that those who have previously been infected with SARS–CoV–2 and are not yet fully vaccinated are at grave danger from SARS–CoV–2 exposure and that it is necessary to protect these workers via vaccination, or testing and the use of face coverings, under this standard. OSHA will continue to follow developments on this issue, however, and make appropriate adjustments to this ETS if the evidence warrants.

VI. Conclusion.

OSHA finds that many employees in the U.S. who are not fully vaccinated against COVID–19 face a grave danger from exposure to SARS–CoV–2 in the workplace. OSHA's determination is based on the severe health consequences of exposure to the virus, including death; powerful lines of evidence demonstrating the transmissibility of the virus in the workplace; and the prevalence of infections in employee populations.

With respect to the grave health consequences of exposure to SARS–CoV–2, OSHA has found that regardless of where and how exposure occurs, COVID–19 can result in death. Even for those who survive a SARS–CoV–2 infection, the virus can cause serious, long-lasting, and potentially permanent health effects. Serious cases of COVID–19 require hospitalization and dramatic medical interventions, and might leave employees with permanent and disabling health effects. Both death and serious cases of COVID–19 requiring hospitalization provide independent bases for OSHA's finding of grave danger. The evidence is clear that the safe and effective vaccines authorized and/or approved for use in the United States greatly reduce the likelihood of these severe outcomes.

The best available evidence on the science of transmission of the virus makes clear that SARS–CoV–2 is transmissible from person to person in shared workplace settings. The likelihood of transmission can be exacerbated by common characteristics of many workplaces, including working indoors, working with others for extended periods of time, poor ventilation, and close contact with potentially infectious individuals. The likelihood of transmission in the workplace is also exacerbated by the presence of unvaccinated workers, who are more likely than those who are vaccinated to be infected and transmit the virus to others. Every workplace SARS–CoV–2 exposure or transmission has the potential to cause severe illness or even death, particularly in unvaccinated workers. Taken together, the severe health consequences of COVID–19 and the evidence of its transmission in environments characteristic of the workplaces covered by this ETS demonstrate that exposure to SARS–CoV–2 represents a grave danger to unvaccinated employees in many workplaces throughout the country.

The existence of a grave danger to employees from SARS–CoV–2 is further supported by the toll the pandemic has already taken on the nation as a whole and the number of workers who remain unvaccinated. Although OSHA cannot state with precision the total number of workers in our nation who have contracted COVID–19 at work and became sick or died, COVID–19 has killed 723,205 people in the United States as of October 18, 2021 (CDC, October 18, 2021—Cumulative US Deaths). That death toll includes 131,478 people who were 18 to 64 years old, prime working age (CDC, October 18, 2021—Demographic Trends, Deaths by Age Group). OSHA estimates that there are over 26 million workers subject to the rule who remain unvaccinated at present and therefore are in grave danger. As a result of this ETS, the agency estimates that 72% of them will be vaccinated (see OSHA, October 2021c).

Current mortality data shows that unvaccinated people of working age have a 1 in 202 chance of dying when they contract COVID–19 (CDC, October 18, 2021—Demographic Trends, Cases by Age Group; Demographic Trends, Deaths by Age Group). As of October 18, 2021, close to 45 million people in the United States have been reported to have infections, and thousands of new cases were being identified daily (CDC, October 18, 2021—Daily Cases).One in 14 reported cases of COVID–19 in people ages 18 to 64 becomes severe and requires hospitalization (CDC, October 18, 2021—Demographic Trends, Cases by Age; Total Hospitalizations, by Age). Moreover, public health officials agree that these numbers fail to show the full extent of the deaths and illnesses from this disease, and racial and ethnic minority groups are disproportionately represented among COVID–19 cases, hospitalizations, and deaths (CDC, December 10, 2020; CDC, May 26, 2021; Escobar et al., February 9, 2021; Gross et al., October 2020; McLaren, June 2020; CDC, October 6, 2021). Given this context, OSHA is confident in its finding that exposure to SARS–CoV–2 poses a grave danger to the employees covered by this ETS.

The above analysis fully satisfies the OSH Act's requirements for finding a grave danger. Although OSHA usually performs a quantitative risk assessment based on extrapolations among exposure levels before promulgating a health standard under section 6(b)(5) of the OSH Act (29 U.S.C. 655(b)(5)), that type of analysis is not necessary in this situation. OSHA has most often invoked section 6(b)(5) authority to regulate exposures to chemical hazards involving much smaller populations, many fewer cases, extrapolations from animal evidence, long-term exposure, and delayed effects. In those situations, mathematical modelling is necessary to evaluate the extent of the risk at different exposure levels. The gravity of the danger presented by a disease with acute effects like COVID–19, on the other hand, is made obvious by a straightforward count of deaths and illnesses caused by the disease, which reach sums not seen in at least a century. The evidence compiled above amply supports OSHA's finding that SARS–CoV–2 presents a grave danger in American workplaces. In the context of ordinary 6(b) rulemaking, the Supreme Court has said that the OSH Act is not a ''mathematical straitjacket,'' nor does it require the agency to support its findings ''with anything approaching scientific certainty,'' particularly when operating on the ''frontiers of scientific knowledge'' (*Indus. Union Dep't, AFL–CIO* v. *Am. Petroleum Inst.*, 448 U.S. 607, 655–56 (1980)). This is true *a fortiori* in the current national crisis, where OSHA must act to ensure employees are adequately protected from the hazard presented by the COVID–19 pandemic (see 29 U.S.C 655(c)(1)).The grave danger from SARS–CoV–2 represents the biggest threat to employees in OSHA's more than 50-year history. The threat applies to employees in all sectors covered by OSHA, including general industry, construction, maritime, agriculture, and healthcare. Having made the determination of grave danger, as well as the determination that an ETS is necessary to protect employees from exposure to SARS–CoV–2 (see *Need for the ETS*, Section III.B. of this preamble), OSHA is required to issue this standard to protect employees from getting sick or dying from COVID–19 acquired at work (see 29 U.S.C. 655(c)(1)).

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B. Need for the ETS

This ETS is necessary to protect unvaccinated workers from the risk of contracting COVID–19, including its more contagious variants, such as the B.1.617.2 (Delta), at work. The rule protects workers through the most effective and efficient workplace control available: Vaccination. Additionally, this ETS is necessary to protect workers who remain unvaccinated through required regular testing, use of face coverings, and removal of infected employees from the workplace.

I. Events Leading to the ETS

This section describes the evolution of OSHA's actions to protect employees from the grave danger posed by COVID–19 and the agency's reasons for issuing this ETS at this time.

a. OSHA's 2020 Actions Regarding COVID–19

Beginning in early 2020, OSHA began to monitor the growing cases of the SARS–CoV–2 virus that were occurring around the country. Because scientific information about the disease, its potential duration, and ways to mitigate it were undeveloped, OSHA decided to monitor the situation. As noted below, OSHA subsequently issued numerous guidance documents advising interested employers of steps they could take to mitigate the hazard arising from the virus.

Also beginning in early 2020, OSHA received numerous petitions and supporting letters from members of Congress, unions, advocacy groups, and one group of large employers urging the agency to take immediate action by issuing an ETS to protect employees from exposure to the virus that causes COVID–19 (Scott and Adams, January 30, 2020; NNU, March 4, 2020; AFL–CIO, March 6, 2020; Menendez et al., March 9, 2020; Wellington, March 12, 2020; DeVito, March 12, 2020; Carome, March 13, 2020; SMART, March 30, 2020; Blumenthal et al., April 8, 2020; Murray et al., April 29, 2020; Luong, April 30, 2020; Novoa, June 24, 2020; Solt, April 28, 2020; Castro et al., April 29, 2020; Talbott and Adely, May 4, 2020; Public Citizen, March 13, 2020;

LULAC, March 31, 2020; Meuser, May 1, 2020; Raskin, April 29, 2020; Cartwright et al., May 7, 2020; Frosh et al., May 12, 2020; Pellerin, March 19, 2020; Yborra, March 19, 2020; Owen, March 19, 2020; Brown et al., April 30, 2020; Price et al., May 1, 2020; ORCHSE, October 9, 2020). These petitions and supporting letters argued that many employees had been infected because of workplace exposures to the virus that causes COVID–19, and that immediate, legally enforceable action is necessary for protection. OSHA quickly began issuing detailed guidance documents and alerts beginning in March 2020 that helped employers to determine employee risk levels of COVID–19 exposure and made recommendations for appropriate controls. As explained in detail in Section IV. of the Healthcare ETS, 86 FR 32376, 32412–13 (June 21, 2021) and hereby included in the record for this ETS,[16] at the time, OSHA leadership believed that implementing a combination of enforcement tools, including guidance, existing OSHA standards, and the General Duty Clause, would provide the necessary protection for workers. OSHA also expressed concern that an ETS might unintentionally enshrine requirements that are subsequently proven ineffective in reducing transmission.

When it decided not to issue an ETS in the spring of 2020, OSHA determined that the agency could provide sufficient employee protection against COVID–19 through enforcing existing workplace standards and the General Duty Clause of the OSH Act, coupled with issuing industry-specific, non-mandatory guidance. However, in doing so OSHA indicated that its conclusion that an ETS was not necessary was specific to that time, and that the agency would continue to monitor the situation and take additional steps as appropriate (see, *e.g.,* OSHA, March 18, 2020 Letter to Congressman Scott (stating ''[W]e currently see no additional benefit from an ETS in the current circumstances relating to COVID–19. OSHA is continuing to monitor this quickly evolving situation and will take the appropriate steps to protect workers from COVID–19 in coordination with the overall U.S. government response effort.'' (emphasis supplied); DOL May 29, 2020 at 20 (stating ''OSHA has determined this steep threshold [of necessity] is not met here, at least not at this time.'' (emphasis supplied))).

In addition to the various petitions for rulemaking that were submitted to OSHA, the AFL–CIO filed a petition for a writ of mandamus with the U.S. Court of Appeals for the D.C. Circuit, requesting that the court compel OSHA to issue an ETS. (AFL–CIO, May 18, 2020). In its administrative decision and filing in that case, OSHA explained that the determination not to issue an ETS was based on the conditions and information available to the agency at that time and was subject to change as additional information indicated the need for an ETS. On June 11, 2020, the U.S. Court of Appeals for the D.C. Circuit issued a one paragraph per curiam order denying the AFL–CIO's petition to require OSHA to issue an ETS. To be clear, nothing in OSHA's prior position or the D.C. Circuit's decision in In re Am. Fed'n of Labor & Cong. of Indus. Orgs., No. 20–1158, 2020 WL 3125324 (D.C. Cir. June 11, 2020); rehearing en banc denied (July 28, 2020) precludes OSHA's decision to promulgate an ETS now. To the contrary, at an early phase of the pandemic, when vaccines were not yet available and when it was not yet known how extensive the impact would be on illness and death, the court decided not to second-guess OSHA's decision to hold off on regulation in order to see if its nonregulatory enforcement tools could be used to provide adequate protection against the virus. ''OSHA's decision not to issue an ETS is entitled to considerable deference,'' the court explained, noting ''the unprecedented nature of the COVID–19 pandemic'' and concluding merely that ''OSHA reasonably determined that an ETS is not necessary at this time.'' (Id., with emphasis added).

Employers do not have a reliance interest in OSHA's prior decision not to issue an ETS on May 29, 2020, which did not alter the status quo or require employers to change their behavior. See *Dep't of Homeland Security* v. *Regents of the Univ. of California*, 140 S. Ct. 1891, 1913–14 (2020). As OSHA indicated when it made the decision, the determination was based on the conditions and information available to the agency at that time and was subject to change as additional information indicated the need for an ETS. In light of the agency's express qualifications and the surrounding context, any employer reliance would have been unjustified and cannot outweigh the countervailing urgent need to protect workers covered by this ETS from the grave danger posed by COVID–19.

b. OSHA's Decision To Promulgate a Healthcare ETS

OSHA subsequently issued the Healthcare ETS to protect healthcare workers. 86 FR 32376. (June 21, 2021), codified at 29 CFR 1910.502. Looking back on a year of experience, OSHA found that its enforcement efforts had encountered significant obstacles, demonstrating that existing standards, regulations, and the General Duty Clause were inadequate to address the grave danger faced by healthcare employees. 86 FR 32415. In promulgating that ETS, OSHA recognized that ''the impact of [COVID–19] has been borne disproportionately by the healthcare and healthcare support workers tasked with caring for those infected by this disease.'' 86 FR 32377. Furthermore, states and localities had taken increasingly divergent approaches to workplace protections against COVID–19, making it clear that a federal standard was needed to ensure sufficient protection in all states. 86 FR 32377. Therefore, OSHA focused on the unique situation experienced by healthcare industry workers as the frontline caregivers and support workers for those suffering from COVID–19. See 86 FR 32376, 32411–12.

The Healthcare ETS requires employers to institute a suite of engineering controls, administrative controls, work practices, and personal protective equipment to combat the COVID–19 hazard. In the Preamble to the Healthcare ETS, OSHA observed that the development of safe and highly effective vaccines is a critical milestone in the nation's response to COVID–19, and that fully vaccinated persons have a greatly reduced risk of death, hospitalization and other health consequences. 86 FR 32396. The Healthcare ETS therefore includes provisions intended to encourage employees to become vaccinated, including a requirement for employers to provide reasonable paid leave for vaccination and recovery from any side effects. 86 FR 32415, 29 CFR 1910.502(m).

In the Healthcare ETS OSHA found that employees who work in covered healthcare workplaces are exposed to grave danger. 86 FR 32411. The agency also stated that in light of the effectiveness of vaccines, there was ''insufficient evidence in the record to support a grave danger finding for non-healthcare workplaces *where all employees are vaccinated*.'' 86 FR 32396 (emphasis supplied). OSHA made no finding at that time regarding unvaccinated workers in non-healthcare workplaces.

[16] This adoption includes the citations in the referenced section of the Healthcare ETS, which are also included in the docket for this ETS.

No employer challenged the Healthcare ETS in court. The United Food and Commercial Workers Union (UFCW) together with the AFL–CIO filed a petition for review asserting that the rule should have gone further and included more industries in its scope (UFCW and AFL–CIO, June 24, 2021). That case is being held in abeyance pending the issuance of this ETS.

c. Subsequent Developments

The preamble to the Healthcare ETS notes that new COVID–19 variants might emerge that are more transmissible and cause more severe illness, but does not specifically mention the Delta Variant. See 86 FR 32384. Since publication of the Healthcare ETS, the Delta Variant has become the dominant form of the virus in the United States, causing large spikes in transmission, and surges of hospitalizations, and deaths, overwhelmingly among the unvaccinated (CDC, August 26, 2021; CDC, October 18, 2021—Variant Proportions, July Through October, 2021). As discussed in more detail in Grave Danger (Section III.A. of this preamble), the Delta Variant is at least twice as contagious as previous COVID–19 variants, and research suggests that it also causes more severe illness in the unvaccinated population (CDC, August 26, 2021). More infections mean more potential for exposures, including in workplaces (see Grave Danger, Section III.A. of this preamble, for further discussion on workplace outbreaks, clusters, and the general impact of transmission in the workplace.). More infections also mean more opportunities for the virus to undergo mutations to its genetic code, resulting in genetic variants with the potential to infect or re-infect people.

Some variability in infection rates in a pandemic is to be expected. While the curves of new infections and deaths can bend down after peaks, they often reverse course only to reach additional peaks in the future (Moore et al., April 30, 2020). Last year experts expressed concern that one or more subsequent waves of COVID–19 were possible in 2021 (Moore et al., April 30, 2020), especially with new variants of COVID–19 in circulation (Doughton, February 9, 2021). That potential tragically became a reality with the spread of the Delta Variant.

In June 2021, when the Healthcare ETS was published, COVID–19 transmission rates in the United States were at a low point, with the 7-day moving average of reported cases to be about 12,000. (CDC, August 26, 2021) However, by the end of July, the 7-day moving average reached over 60,000 as the Delta Variant spread across the country. (CDC, August 26, 2021). The 7-day moving average of reported cases at the beginning of September, 2021 exceeded 161,000 (CDC, October 18, 2021—Daily Cases). The most recent 7-day moving average of reported cases, while lower than the peak in late August and early September, is still over 85,000. (CDC, October 18, 2021—Daily Cases). These rates are also far higher than the rate when OSHA first declined to issue an ETS. (CDC, August 27, 2020 (20,401 confirmed cases per day on May 29, 2020)). The jump in infections has resulted in increased hospitalizations and deaths for unvaccinated workers, as discussed in detail in Grave Danger (Section III.A. of this preamble). While the most current data reflect a decline in new cases from the peak, the level of new cases remains high. CDC data shows that, as of October 18, 2021, approximately 85% of U.S. counties were experiencing ''high'' rates of community transmission, and another 10% were experiencing ''substantial'' community transmission (CDC, October 18, 2021—Daily Cases). Although the number of new detected cases is currently declining nationwide (see CDC, October 18, 2021—Community Transmission Rates), the agency cannot assume based on past experience that nationwide case levels will not increase again. Indeed, many northern states are currently experiencing increases in their rate of new cases (see CDC, October 18, 2021—Cases, Deaths, and Laboratory Testing (NAATS) by State; Slotnik, October 18, 2021), including Vermont, which set a new record for new COVID–19 cases in mid-October 2021 (Murray, October 18, 2021). Unless vaccination rates increase, the experience of northern states during this fall could presage a greater resurgence in cases this winter as colder weather drives more individuals indoors (see Firozi and Dupree, October 18, 2021).

While it is important to recognize that the Delta Variant has caused a spike in hospitalization and death in the United States, the SARS–CoV–2 virus, and not just a particular variant of that virus, is the hazard that workers face (see Grave Danger, Section III.A. of this preamble). Like any virus, SARS–CoV–2 has the ability to mutate over time and produce variants that may be more or less severe. Indeed, the World Health Organization and the CDC both track new variants that have continued to arise, such as the Lamda and Mu Variants (WHO, October 12, 2021; CDC, October 4, 2021). At this time, the CDC is tracking 11 different variants of COVID–19 (CDC, October 4, 2021). The World Health Organization has classified the Lambda and Mu variants as ''variants of interest,'' meaning that they have genetic changes that affect transmissibility, disease severity, immune escape, diagnostic or therapeutic escape; and have been identified to cause significant community transmission or multiple COVID–19 clusters, in multiple countries with increasing relative prevalence alongside increasing number of cases over time, or other apparent epidemiological impacts to suggest an emerging risk to global public health (WHO, October 12, 2021). Medical experts have also explained that vaccination reduces the opportunities for the virus to continue to mutate by reducing transmission and length of infection. And, there is no indication that future variants of COVID–19 will not be equally or even more dangerous than Delta without a higher rate of vaccination (Bollinger and Ray, July 23, 2021).

Meanwhile, evidence on the power of vaccines to safely protect individuals from infection and especially from serious disease has continued to accumulate. (CDC, May 21, 2021). For example, as explained in more detail in Grave Danger (Section III.A. of this preamble), multiple studies have demonstrated that vaccines are highly effective at reducing instances of hospitalization and death. In September the CDC compiled data from various studies that demonstrated overall authorized vaccines reduced death and severe case rates by 91 and 92% respectively in the population studied between April and July (Scobie et al., September 17, 2021, Table 1.). Additionally, the FDA granted approval to the Pfizer-BioNTech COVID–19 Vaccine for individuals 16 years of age and older on August 23, 2021 (FDA, August 23, 2021). In announcing the decision, the FDA Commissioner explained that ''[w]hile this and other vaccines have met the FDA's rigorous, scientific standards for emergency use authorization, as the first FDA-approved COVID–19 vaccine, the public can be very confident that this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product.'' (FDA, August 23, 2021.)

Despite this important milestone, and the demonstrated effectiveness of the approved and authorized vaccines available to the public, millions of employees remain unvaccinated, approximately 39% of workers who are covered by this ETS (See Economic Analysis, Section IV.B. of this ETS). The rate of vaccination in the United States

has slowed significantly from its peak in April, when the daily number of vaccination doses administered exceeded three million at one point. In recent months, daily vaccination rates have hovered around one million doses administered, or lower (CDC, October 18, 2021—Daily Vaccination Rate). The shortfall in vaccination leaves the nation's working population vulnerable to sickness, hospitalization and death, whether today under the Delta Variant, or under future variants that may arise (CDC, October 18, 2021—Daily Vaccination Rate); see also Grave Danger (Section III.A. of this preamble).

Moreover, in recent months, an increasing number of states have promulgated Executive Orders or statutes that prohibit workplace vaccination policies that require vaccination or proof of vaccination status, thus attempting to prevent employers from implementing the most efficient and effective method for protecting workers from the hazard of COVID–19 (see, *e.g.,* Texas Executive Order GA–40, October 11, 2021; Montana H.B. 702, July 1, 2021; Arkansas S.B. 739, October 4, 2021 and Arkansas H.B. 1977, October 1, 2021; AZ Executive Order 2021–18, August 16, 2021). While some States' bans have focused on preventing local governments from requiring their public employees to be vaccinated or show proof of vaccination, the Texas, Montana, and Arkansas requirements apply to private employers as well. Other states have banned local ordinances that require employers to ensure that customers who enter their premises wear masks, thus endangering the employees who work there, particularly those who are unvaccinated (see, *e.g.,* Florida Executive Order 21–102, May 3, 2021; Texas Executive Order GA–34, March 2, 2021).

In short, at the present time, workers are becoming sick and dying unnecessarily as a result of occupational exposures, when there is a simple and effective measure, vaccination, that can largely prevent those deaths and illnesses (see *Grave Danger*, Section III.A. of this preamble). Congress charged OSHA with responsibility for issuing emergency standards when they are necessary to protect employees from grave danger. 29 U.S.C. 655(c). In light of the current situation, OSHA is issuing this emergency rule.

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II. This ETS Is Necessary To Protect Unvaccinated Employees From Grave Danger

As explained at length in the preceding section (*Grave Danger*, Section III.A. of this preamble), OSHA has determined that most unvaccinated workers across the U.S. economy are facing a grave danger posed by the COVID–19 hazard.[17] This new hazard has taken the lives of more than 725,000 people—many of them workers—in the United States since it was first detected in this country in early 2020. As the federal agency tasked with protecting the safety and health of workers in the United States, OSHA is required to act when it finds that workers are exposed to a grave danger. 29 U.S.C. 655(c)(1). OSHA now finds that this emergency temporary standard is necessary to protect employees who are unvaccinated. Asbestos Info. Ass'n, 727 F.2d at 423 (''failure to act does not conclusively establish that a situation is not an emergency . . . [when there is a grave danger to workers,] to hold that because OSHA did not act previously it cannot do so now only compounds the consequences of the Agency's failure to act.''). As explained in detail below, OSHA has determined that vaccination is the most effective control for abating the grave danger that unvaccinated employees face from the COVID–19 hazard. And, for workers who are not vaccinated, the use of testing, face coverings, and removal from the workplace, while not as effective as vaccination, is still effective and necessary.

OSHA has determined that the best method for addressing the grave danger that COVID–19 poses to unvaccinated workers is to strongly encourage the use of the single most effective and efficient protection available: Vaccination. OSHA

[17] As explained in the Grave Danger section, this ETS focuses on protecting unvaccinated workers from the grave danger that COVID–19 poses in the workplace. OSHA did not include fully vaccinated workers in its finding of grave danger because such workers are generally much better protected from the effects of COVID–19, and, in particular, the most severe effects, than workers who are unvaccinated. OSHA's action in adopting this ETS for unvaccinated workers does not mean that vaccinated workers do not face a significant risk from COVID–19, or that the OSH Act's general duty clause poses no obligation on employers to protect their vaccinated workers from COVID–19. Indeed, symptomatic infections can occur in fully vaccinated people, and COVID–19 therefore poses at least some risk to vaccinated workers. OSHA has requested comment on the risks faced by vaccinated workers from COVID–19, and what additional measures, if any, should be taken to protect both vaccinated and unvaccinated workers (see Request for Comments, Section I.B. of this preamble).

has long recognized the importance of vaccinating workers against preventable illnesses to which they may be exposed on the job. See 56 FR 64004, 64152 (Dec. 6, 1991) (discussing requirement in Bloodborne Pathogens standard for employer to make hepatitis B vaccine available to any employees with occupational exposure to blood and other potentially infectious materials). As explained in *Grave Danger* (Section III.A. of this preamble), COVID–19 vaccines do not completely eliminate the potential for infection, but significantly reduce the likelihood of infection, and in turn, transmission of the virus to others. Data from clinical trials for all three vaccines and observational studies for the two mRNA vaccines clearly establish that fully vaccinated persons have a greatly reduced risk of SARS–CoV–2 infection compared to unvaccinated individuals (see FDA, December 11, 2020; FDA, December 18, 2020; FDA, February 26, 2021).

More importantly, vaccination is the single most effective method for protecting workers from the most serious consequences of a COVID–19 infection: Hospitalization and death. Although symptomatic infections can occur in fully vaccinated people, they are less likely to occur, and are far less likely to result in severe health outcomes or death. As discussed in *Grave Danger* (Section III.A. of this preamble), studies have established that the available COVID–19 vaccines are highly effective at preventing hospitalization, and even more effective at preventing death. For example, one study found that unvaccinated adults age 18 to 49 were 15.2 times more likely to be hospitalized and 17.2 times more likely to die of COVID–19 than fully vaccinated people in the same age range, and unvaccinated adults age 50 to 64 were 10.9 times more likely to be hospitalized and 17.9 times more likely to die than their fully vaccinated peers (Scobie et al., September 17, 2021). The New York Times reported on October 1, 2021, that of the approximately 100,000 individuals who died of COVID–19 since mid-June 2021, less than 3% had been identified by the CDC as vaccinated individuals (Boseman and Leatherby, October 1, 2021).

Vaccines are also uniquely effective when compared to non-pharmaceutical methods for controlling exposure to COVID–19 at the workplace. To be sure, non-pharmaceutical controls play an important role in employers' efforts to prevent exposure to the virus; as discussed in detail earlier, OSHA has, throughout the pandemic, advised employers to implement various administrative, engineering, and other controls to reduce workplace exposure to the virus. And, for certain work settings in the healthcare industry where people with COVID–19 are reasonably expected to be present, OSHA both encouraged vaccination and mandated a suite of protections, many of which involve physical controls (see 29 CFR 1910.502). Indeed, workers who work indoors and near others are best protected from COVID–19 when they are fully vaccinated and their exposure to COVID–19 is reduced (to the extent possible) by non-pharmaceutical controls.

Non-pharmaceutical controls, however, focus on preventing employee exposure to the virus, and do not directly affect an employee's immune response if exposure to the virus does occur. Additionally, non-pharmaceutical controls often rely on the actions of individuals and/or the integrity of equipment to be effective; for example, to use PPE to control exposure, a worker must correctly don appropriate PPE each time there is potential exposure, must properly clean, store, and maintain the PPE between uses, and must replace the PPE when it is no longer effective (see, *e.g.,* 29 CFR 1910.132 (general PPE requirements in general industry workplaces)). Accordingly, OSHA standards have always followed the principle of the hierarchy of controls, under which employers must control hazards by means other than PPE whenever feasible, and PPE is a supplementary control. See *e.g.*, 29 CFR 1910.134(a); 29 CFR 1910.1030(d)(2).

Physical distancing requires workers to maintain constant awareness of their environment in order to avoid coming into close proximity with colleagues, customers, or other individuals, even though the realities of their jobs and/or the design of the workplace may be unaccommodating to that effort. Requiring employees to examine themselves for signs and symptoms consistent with SARS–CoV–2 infection before reporting to work is prone to human error and entirely ineffective when the employee is infected but asymptomatic or pre-symptomatic.

In contrast, a worker is considered fully vaccinated after completing primary vaccination with a COVID–19 vaccine, or the second dose of any combination of two doses of a COVID–19 vaccine that is approved, authorized, or listed as a two-dose primary vaccination by the FDA or WHO (see the *Summary and Explanation* for paragraph (c), Section VI.C. of this preamble). Once fully vaccinated, a worker enjoys automatic and long-lasting benefits; namely, a drastic reduction in the risk of severe health effects or death. The vaccine works by bolstering the worker's immune system and does not depend on the worker's acumen or actions to afford its protection. Moreover, where an employer implements one or more non-pharmaceutical controls at the workplace, vaccination provides workers with a backstop of protection that greatly reduces their risk of serious health effects if they are exposed to the virus despite the presence of other controls. Vaccination thus ensures that workers need not rely on other factors, be it the workplace environment, the effectiveness of equipment, or the actions of other individuals, to be substantially protected from the worst potential outcomes of a COVID–19 infection.

This ETS focuses on encouraging vaccination because it is the most efficient and effective method for addressing the grave danger. Vaccination is patently appropriate and feasible for almost every worker in all industries, and will drastically reduce the risk that unvaccinated workers will suffer the serious health outcomes associated with SARS–CoV–2 infection. As described in Section III.A. of this preamble (*Grave Danger*), employees who are unvaccinated are in grave danger from the SARS–CoV–2 virus, but employees who are fully vaccinated are not. Since it is the lack of vaccination that results in grave danger, vaccination will best allay the grave danger. This ETS, which is designed to strongly encourage vaccination, is thus ''necessary to protect employees'' from a grave danger. 29 U.S.C. 655(c).

OSHA continues to encourage employers to implement additional controls that may be appropriate to eliminate exposure to the SARS–CoV–2 virus at their workplace, but, as discussed further below, OSHA has not required employers to implement a comprehensive and multilayered set of COVID–19 exposure controls in this ETS. This decision reflects the extraordinary and exigent circumstances have required OSHA to immediately promulgate this emergency temporary standard. Although OSHA was able to design a comprehensive infection prevention program for the specific healthcare settings to which the June 2021 Healthcare ETS applied, this rule encompasses all industries covered by the OSH Act, and targets unvaccinated workers in any indoor work setting not covered by the Healthcare ETS where more than one person is present. Crafting a multi-layered standard that is comprehensive and feasible for all

covered work settings, including mixed settings of vaccinated and unvaccinated workers, is an extraordinarily challenging and complicated undertaking, yet the grave danger that COVID–19 poses to unvaccinated workers obliges the agency to act as quickly possible. As discussed above, OSHA has identified vaccination as the single most efficient and effective means for removing an unvaccinated worker from the grave danger.

Given the urgency of the rulemaking, and the singular effectiveness of vaccination in removing unvaccinated workers from the grave danger, OSHA is promulgating this ETS to immediately address the grave danger that COVID–19 poses to unvaccinated workers by strongly encouraging vaccination. As discussed in *Pertinent Legal Authority* (Section II. of this preamble), a ''grave danger'' represents a risk greater than the ''significant risk'' that OSHA must show in order to promulgate a permanent standard under section 6(b) of the OSH Act, 29 U.S.C. 655(b). OSHA will consider whether it is necessary to require additional controls to avert a significant risk of harm in the rulemaking proceedings that follow this ETS. OSHA directs employers to its website, *www.osha.gov/coronavirus*, and the CDC's website, *www.cdc.gov/coronavirus*, for guidance on the engineering, administrative, and other exposure controls that may be effective and appropriate for their workplace.

OSHA expects that, by strongly encouraging vaccination, this ETS will have a positive impact on worker health. As discussed above, millions of workers remain unvaccinated and are presently exposed to risks of hospitalization and death many times higher than their vaccinated coworkers. Although predicting the health impact of this ETS is particularly challenging, given the ever-changing nature of the pandemic and the many factors that may motivate workers to become fully vaccinated, OSHA has attempted to quantify the potential number of hospitalizations and fatalities that this ETS could avert by increasing workforce vaccination rates (see OSHA, October 2021c). OSHA has estimated that, as a result of the ETS, over 6,500 fewer currently unvaccinated workers will die from COVID–19 over the next six months. OSHA also estimates that this ETS will prevent over 250,000 currently unvaccinated workers from being hospitalized during that same time period. Even if OSHA's estimate does not prove to be precisely accurate, OSHA is confident that this ETS will save hundreds of lives and prevent thousands of workers from becoming severely ill.

a. OSHA Finds It Necessary To Strongly Encourage Vaccination

Despite the proven safety and efficacy of the available COVID–19 vaccines, many workers remain unvaccinated and are currently exposed to a grave danger. As discussed in *Grave Danger* (Section III.A. of this preamble), countless COVID–19 outbreaks have occurred in myriad work settings where employees come into contact with others, and in recent weeks, the majority of states in the U.S. have experienced what CDC defines as high or substantial community transmission, indicating that there is a clear risk of the virus being introduced into and circulating in workplaces (CDC, October 18, 2021—Community Transmission Rates). As of October 18, 2021, more than 184 million people in the United States have been fully vaccinated, but only 68.5% of people ages 18 years or older are fully vaccinated (CDC, October 18, 2021—Fully Vaccinated). OSHA has estimated that approximately 62.4% percent of adults aged 18–74 within the scope of this ETS are either fully vaccinated or received their first vaccine dose during the previous two weeks, leaving approximately 31.7 million unvaccinated (*i.e.*, not fully vaccinated and did not receive a first dose with in the past two weeks) (see *Economic Analysis*, Section IV.B. of this preamble, Table IV.B.7). Meanwhile, the rate of new vaccinations has slowed considerably; on October 15, 2021, the 7-day moving average number of administered vaccine doses reported to the CDC per day was 841,731 doses, a steep reduction from the peak 3,448,156 dose average that the CDC reported on April 11, 2021 (CDC, October 18, 2021—Weekly Review).

Given the pervasiveness of the virus in workplaces across the country and the unparalleled efficacy of vaccines at preventing serious health effects, OSHA finds it necessary to strongly encourage vaccination. Encouraging vaccination is principally necessary to reduce the likelihood that workers who are infected by the SARS–CoV–2 virus will suffer the worst outcomes of an infection (hospitalization and death). Put simply, the single best method for protecting an unvaccinated worker from the serious health consequences of a COVID–19 infection is for that worker to become fully vaccinated.

Additionally, encouraging vaccination is necessary to reduce the overall prevalence of the SARS–CoV–2 virus at workplaces. Because vaccinated workers are less likely than unvaccinated workers to be infected by the virus, they are less likely to spread the virus to others at their workplace, including to unvaccinated coworkers. Increasing workforce vaccination rates will therefore reduce the risk that unvaccinated workers will be infected by a coworker.

Evidence shows that mandating vaccination has proven to be an effective method for increasing vaccination rates, and that vaccination mandates have generally been more effective than merely encouraging vaccination. Significant numbers of workers would get vaccinated if their employers required it, and many workers who were vaccinated over the last four months were motivated by their employer requiring vaccination. The Kaiser Family Foundation (KFF) vaccine monitor, an ongoing research project tracking the public's attitudes and experiences with COVID–19 vaccinations, conducted a survey from September 13 to September 22, 2021, among a nationally representative random digit dial telephone sample of 1,519 adults ages 18 and older, and found that those who received their first dose of a COVID–19 vaccine after June 1, 2021 were motivated by mandates of various sorts, including one in five (19%) who say a major reason was that their employer required it (KFF, September 2021). A survey conducted by Change Research from August 30 to September 2, 2021 regarding Americans' views on COVID–19 vaccines found that among the 1,775 respondents, ''one of the things that was most likely to lead someone to get vaccinated was if their employer required it'' (Towey, September 27, 2021).

Vaccine mandates imposed by state governments and large employers have also demonstrated the effectiveness of mandates in increasing vaccination rates. For example, when Tyson Foods announced its vaccination requirement in early August 2021, only 45% of its workforce had received a vaccination dose, but as of September 30, 2021, the New York Times reported that has increased to 91% (White House, October 7, 2021; Hirsch, September 30, 2021). Similarly, United Airlines reported that 97% of its U.S.-based employees were fully vaccinated against COVID–19 within a week of the deadline of the company's vaccination mandate, and the 3% who were not fully vaccinated included several employees who sought a medical or religious exemption from vaccination (The Associated Press, September 22, 2021). In Washington State, the weekly vaccination rate increased 34% after the Governor announced vaccine requirements for

state workers (White House, October 7, 2021). The success of these COVID–19 vaccination mandates comports with the National Safety Council's recent finding that employers that instituted a COVID–19 vaccination mandate produced a 35% increase in employee vaccination (NSC, September 2021). Similarly, the White House recently reported that its analysis of vaccination requirements imposed by healthcare systems, educational institutions, public-sector agencies, and private businesses demonstrated that such requirements increased their vaccination rates by more than 20 percentage points and have routinely seen their share of fully vaccinated workers rise above 90 percent (White House, October 7, 2021).

Given the effectiveness of vaccination mandates in increasing vaccination rates, OSHA expects that, in most instances, an employer implementing a policy that requires all employees to be vaccinated will be the most effective approach for increasing the vaccination rate of its employees and ensuring that they have the best protection available against the worst consequences of a COVID–19 infection. Although OSHA may well have the authority to impose a vaccination mandate, OSHA has decided against pursuing strict vaccination requirement and has instead crafted the ETS to strongly encourage vaccination. Employers are in the best position to understand their workforces and the approach that will work most effectively with them to secure employee cooperation and protection. OSHA's traditional practice when including medical procedures, such as medical surveillance testing and vaccinations, in its health standards has been to require the employer to make the medical procedure available to employees, and has viewed mandating those procedures as a measure to avoid if possible. For example, when the agency promulgated its standard regulating occupational exposure to lead, OSHA considered mandating that employees participate in physical examinations and biological monitoring, but ultimately required employers to make them available to employees (see 43 FR 54354, 54450 (Nov. 21, 1978)). OSHA decided against mandating those procedures in part because it believed a voluntary approach would elicit more effective employee participation in the medical program and in part because of the agency's concerns about the Government intruding into a private and sensitive area of workers' lives (43 FR at 54450–51). OSHA has followed that same approach of requiring employers to ''provide'' or ''make available'' medical procedures to employees in numerous subsequent standards, such as the standards for asbestos (29 CFR 1910.1001), benzene (1910.1028), cotton dust (1910.1043), and formaldehyde (1910.1048).

OSHA adhered to this approach when it promulgated the Bloodborne Pathogens standard. The agency considered mandating a Hepatitis B vaccination, but instead required employers to make the Hepatitis B vaccination available to employees. 56 FR 64004, 64155 (Dec. 6, 1991); 29 CFR 1910.1030(f)(1)(i), (f)(2)(i). OSHA explained that the agency may have the legal authority to mandate vaccination, but believed that, under the circumstances, a voluntary vaccination program would ''foster greater employee cooperation and trust in the system'' and ''enhance [ ] compliance while respecting individuals' beliefs and rights to privacy.'' 56 FR at 64155.

In keeping with this traditional practice, the agency has stopped short of including a strict vaccination mandate with no alternative compliance option in this ETS. OSHA has never done so, and if it were to take that step, OSHA believes it more prudent to do so where the agency has ample time to fully assess the potential ramifications of imposing a vaccination mandate on covered employers and employees. Here, exigent circumstances demand that OSHA take immediate action to protect workers from the grave danger posed by COVID–19, but OSHA has not had a full opportunity to study the potential spectrum of impacts on employers and employees, including the economic and health impacts, that would occur if OSHA imposed a strict vaccination mandate with no alternative compliance option. Moreover, employers in their unique workplace settings may be best situated to understand their workforce and the strategies that will maximize worker protection while minimizing workplace disruptions. These considerations persuade the agency that this ETS should afford employers some flexibility in the form of an alternative option to strictly mandating vaccination. In light of the unique and grave danger posed by COVID–19, OSHA has requested comment on whether a strict vaccination mandate is warranted and the agency will consider all the information it receives as it determines how to proceed with this rulemaking (see *Request for Comment*, Section I.B. of this preamble).

Although this ETS does not impose a strict vaccination mandate, OSHA has determined that, to adequately address the grave danger that COVID–19 poses to unvaccinated workers, a more proactive approach is necessary than simply requiring employers to make vaccination available to employees. None of the standards that OSHA promulgated prior to this year concerned an infectious agent as readily transmissible as COVID–19. Standards like the Lead standard do not concern infectious agents that can be transmitted between individuals at a workplace; accordingly, the medical procedures that employers are required to make available under those standards are solely aimed at protecting the health of the worker who is undergoing the procedure. The Bloodborne Pathogens standard concerned exposure to infectious biological agents (Hepatitis B and HIV) that can be transmitted between individuals, but the potential for those agents to be transmitted between workers is minimal in comparison to the SARS–CoV–2 virus; Hepatitis B and HIV are transmitted through blood and certain body fluids, whereas the SARS–CoV–2 virus spreads through respiratory droplets that can travel through the air from worker-to-worker (see *Grave Danger*, Section III.A. of this preamble). Vaccination against COVID–19 is thus particularly important in reducing the potential for workers to become infected and spread the virus to others at the workplace, in addition to protecting the worker from severe health outcomes if they are infected. Moreover, the ease with which the SARS–CoV–2 virus spreads between workers makes it more urgent for workers to be vaccinated, and this urgency contributes to the agency's decision to strongly encourage vaccination.

Accordingly, to further the goal of increasing workforce vaccination rates, this ETS requires employers to implement a mandatory vaccination policy unless they adopt a policy in which employees may either be fully vaccinated or regularly tested for COVID–19 and wear a face covering in most situations when they work near other individuals. Employers have the duty under the OSH Act to provide safe workplaces to their employees, including protecting employees from known hazards by complying with occupational safety and health standards (see 29 U.S.C. 654), and this ETS therefore provides employers with two compliance options for protecting unvaccinated workers from the grave danger posed by COVID–19. But while this ETS offers employers a choice in how to comply, OSHA has presented implementation of a vaccination mandate as the preferred compliance

option; as discussed above, vaccine mandates have proven to be effective in increasing vaccination rates, and OSHA expects that, in most instances, implementing a vaccination mandate will be the most effective method for increasing a workforce's vaccination rate. As discussed below, OSHA also recognizes that requiring that all employees be vaccinated provides more protection to vaccinated workers than regularly testing unvaccinated workers for COVID–19 and requiring them to wear face coverings when they work near others. This ETS will preempt inconsistent state and local requirements, including requirements that ban or limit employers' authority to require vaccination (see the *Summary and Explanation* for paragraph (a), Section VI.A. of this preamble), and will therefore provide the necessary legal authorization to covered employers to implement mandatory vaccination policies, if they choose to comply in this preferred manner.

Although the ETS does not require all covered employers to implement a mandatory vaccination policy, OSHA expects that employers that choose that compliance option will enjoy advantages that employers that opt out of the vaccination mandate option will not. Most obviously, employers with a mandatory vaccination policy will enjoy a dramatically reduced risk that their employees will become severely ill or die of a COVID–19 infection. In addition, employers who implement a vaccination mandate will likely have fewer workers temporarily removed from the workplace due to a COVID–19 positive test; this rule requires all covered employers to remove from the workplace any employee who tests positive for COVID–19 or receives a diagnosis of COVID–19 (see the *Summary and Explanation* for paragraph (h), Section VI.H. of this preamble), and because vaccinated workers are less likely than unvaccinated workers to be infected by the virus, OSHA expects employers with a mandatory vaccination policy will be statistically less likely to be obliged to remove a COVID-positive employee from the workplace in accordance with paragraph (h)(2). Additionally, only employers who decline to implement a mandatory vaccination program are required by the rule to assume the administrative burden necessary to ensure that unvaccinated workers are regularly tested for COVID–19 and wear face coverings when they work near others.

Where employers opt out of implementing a mandatory vaccination program, the ETS encourages employees to elect to be fully vaccinated. As discussed in the *Summary and Explanation* for paragraph (f) (Section VI.F. of this preamble), the ETS requires all covered employers to support vaccination by providing employees with reasonable time, including up to four hours of paid time, to receive each vaccination dose, and reasonable time and paid sick leave to recover from vaccination side effects. Many workers have been deterred from receiving vaccination by fears of missing work and/or losing pay to obtain vaccination and/or recover from side effects (see Section VI.F. of this preamble; see, *e.g.*, KFF, May 6, 2021; KFF, May 17, 2021), and OSHA finds that this employer support is necessary to ensure that employees can become fully vaccinated without concern that they will be sacrificing pay or their jobs to do so.

All covered employers are required by the ETS to bear the cost of providing up to four hours of paid time and reasonable paid sick leave needed to support vaccination, but where an employee chooses to remain unvaccinated, the ETS does not require employers to pay for the costs associated with regular COVID–19 testing or the use of face coverings (see the *Summary and Explanation* for paragraphs (g) and (i), Sections VI.G. and VI.I. of this preamble). In some cases, employers may be required to pay testing and/or face covering costs under other federal or state laws or collective bargaining obligations, and some may choose to do so even without such a mandate, but otherwise employees will be required to bear the costs if they choose to be regularly tested and wear a face covering in lieu of vaccination.

This ETS more strongly encourages vaccination than the June 2021 Healthcare ETS. OSHA designed the Healthcare ETS, which addresses the grave danger that COVID–19 poses workers in specific health care settings where COVID–19-positive individuals are reasonably likely to be present, to encourage vaccination (see 86 FR at 32415, 32423, 32565, 32597). Specifically, the Healthcare ETS encourages vaccination by requiring employers to provide employees reasonable and paid time to receive vaccination doses and recover from side effects (29 CFR 1910.502(m)), and by exempting from its scope ''well-defined hospital ambulatory care settings where all employees are fully vaccinated'' and all non-employees are screened and denied entry if they are suspected or confirmed to have COVID–19 (1910.502(a)(2)(iv)) and ''home healthcare settings where all employees are fully vaccinated'' and all nonemployees at that location are screened prior to employee entry so that people with suspected or confirmed COVID–19 are not present (1910.502 (a)(2)(v)).

Similar to the Healthcare ETS, this ETS requires employers to support vaccination by providing employees with reasonable time, including up to four hours of paid time, to receive vaccination, and reasonable time and paid sick leave to recover from vaccination side effects (see discussion above and the *Summary and Explanation* for paragraph (f), Section VI.F. of this preamble). However, as discussed above, this ETS goes further and expressly requires the implementation of a mandatory vaccination policy, unless the employer implements an alternative policy that requires unvaccinated workers to be regularly tested for COVID–19 and to wear face coverings in most situations when they work near others. While nothing in the Healthcare ETS prohibits covered employers from implementing a mandatory vaccination policy, this ETS presents the implementation of a mandatory vaccination policy as a preferred compliance option, and will preempt inconsistent state and local requirements that ban or limit employers' authority to require vaccination. Additionally, where the employer opts out of implementing a mandatory vaccination policy, and the employee opts out of vaccination, this ETS places no obligation on the employer to pay for costs associated with the regular testing of unvaccinated workers for COVID–19 or their use of face coverings, which will provide a financial incentive for some employees to be fully vaccinated.

OSHA finds it necessary to more strongly encourage vaccination in this ETS than in the Healthcare ETS in the manner described above. The Healthcare ETS's provisions that encouraged vaccination were packaged with a comprehensive infection prevention program that was tailored to the specific healthcare work settings to which the ETS applied, including a suite of layered and overlapping controls. In contrast, OSHA is promulgating this ETS to address the grave danger that COVID–19 now poses to all unvaccinated workers who work indoors and in the presence of others. As mentioned above, crafting a comprehensive and multi-layered standard that is comprehensive and feasible for the myriad work settings to which this ETS will apply, including workplaces as diverse as schools, restaurants, retail settings, offices, prisons, and factories, is an

extraordinarily challenging and complicated undertaking.

Exigent circumstances require OSHA to immediately promulgate this ETS to protect unvaccinated workers, and vaccination is the single most efficient and effective method for removing unvaccinated workers from the grave danger. Given the urgency of the rulemaking and the singular efficacy of vaccination, OSHA has decided against including comprehensive and multilayered exposure controls in this ETS, and is instead focusing the ETS on strongly encouraging vaccination. Strongly encouraging vaccination is thus critical to the effectiveness of this ETS at protecting unvaccinated workers from the grave danger. In *Request for Comment* (Section I.B. of this preamble), OSHA seeks information on what additional measures, if any, should be required to protect employees against COVID–19.

Moreover, stronger encouragement of vaccination is needed in this ETS than in the Healthcare ETS because workers who are protected by the Healthcare ETS are more likely to be vaccinated and/or subject to a vaccination mandate. The Healthcare ETS, 29 CFR 1910.502, focused on healthcare work settings where COVID–19 is reasonably expected to be present, and, this ETS does not apply in settings where any employee provides healthcare services or healthcare support services while they are covered by the requirements of 29 CFR 1910.502 (see the *Summary and Explanation* for paragraph (b), Section VI.B. of this preamble). Evidence shows that workers in settings covered by § 1910.502 already have a high rate of vaccination. As of July 2021, healthcare workers had a higher rate of vaccination than non-healthcare workers (Lazer et al., August, 2021), and many healthcare workers are currently subject to vaccination mandates. Twenty-two states and the District of Columbia have instituted vaccination mandates that are applicable to healthcare workers (NASHP, October 1, 2021), and nearly 300 hospitals and broader health systems have implemented vaccine mandates for their employees (Renton et al., October 14, 2021). The White House reported that almost 2,500 hospitals, 40% of all U.S. hospitals, across all 50 states, the District of Columbia, and Puerto Rico, have announced vaccination requirements for their workforce, and noted numerous examples of highly successful mandates in those workplaces (White House, October 7, 2021). News reports attest that many of these vaccination mandates have had great success in increasing the vaccination rate of the targeted healthcare workers (Goldberg, July 9, 2021; Otterman and Goldstein, September 28, 2021; Hubler, September 30, 2021; Beer, October 4, 2021). Even more healthcare workers covered by 29 CFR 1910.502 will be subject to a vaccination mandate under the Centers for Medicare & Medicaid Services (CMS) rule published elsewhere in this issue of the **Federal Register** that requires COVID–19 vaccinations for workers in most healthcare settings that receive Medicare or Medicaid reimbursement, including but not limited to hospitals, dialysis facilities, ambulatory surgical settings, and home health agencies. This CMS rule applies to at least 76,000 providers (i.e., employers) and covers a majority of healthcare workers across the country. OSHA expects that the combination of incentives to vaccination in the Healthcare ETS and vaccination mandates applicable to healthcare workers will leave few healthcare workers within the scope of the Healthcare ETS unvaccinated.

b. Unvaccinated Workers Must Be Regularly Tested for COVID–19 and Use Face Coverings

As discussed above, this ETS presumptively requires employers to implement a mandatory vaccination policy, but permits employers to opt out of that requirement. Nonetheless, the grave danger that COVID–19 poses to unvaccinated workers demands that alternative protective measures be taken at workplaces where the employer does not implement a mandatory vaccination policy. Given that the SARS–CoV–2 virus is highly contagious, transmitted easily through the air, and can lead to severe and/or fatal outcomes in unvaccinated workers, it is critical that employers who do not require their employees to be vaccinated implement controls to mitigate the potential for COVID–19 outbreaks to occur. As discussed above, and in *Grave Danger* (Section III.A. of this preamble), unvaccinated workers are more likely than vaccinated workers to be infected with COVID–19 and transmit the virus to others, and thus pose a heightened risk of spreading the virus at the workplace, including to other unvaccinated workers.

To reduce the risk that unvaccinated workers will spread COVID–19 at the workplace, this rule requires employers that do not implement a mandatory vaccination policy to ensure that unvaccinated workers who report to a workplace where others are present are tested at least once a week for COVID–19. As discussed in the *Summary and Explanation* for paragraph (g) (Section VI.G. of this preamble), it is well-established that, by identifying and isolating infected individuals, regularly testing individuals for COVID–19 infection can be an effective method for reducing virus transmission. Regularly testing unvaccinated workers is essential because SARS–CoV–2 infection is often attributable to asymptomatic or presymptomatic transmission (Bender et al., February 18, 2021; Byambasuren et al., December 11, 2020; Johansson et al., January 7, 2021; Klompas et al., September 2021). In accordance with the CDC's recommendations, OSHA has set the minimum frequency of testing at 7 days because the agency expects that it will be effective in slowing the spread of COVID–19, while taking into account associated cost considerations (see the *Summary and Explanation* for paragraph (g), Section VI.G. of this preamble). As noted in the *Request for Comment* (Section I.B. of this preamble), OSHA is gathering additional information about whether OSHA should require testing more often than on a weekly basis.

The requirement for unvaccinated workers to be regularly tested for COVID–19 operates in tandem with paragraph (h)(2), which requires that all employers remove from the workplace any employee who receives a positive COVID–19 test, or a COVID–19 diagnosis (see the *Summary and Explanation* for paragraph (h), Section VI.H. of this preamble). Paragraph (h)(2) ensures that the COVID–19-positive employee will be isolated from the workplace until it is safe for the employee to return, and also allows the employee to seek medical care sooner and reduce the likelihood that they will suffer the most severe consequences of an infection (*e.g.*, by seeking monoclonal antibody treatment). The combination of the testing and medical removal provisions will reduce the likelihood that an unvaccinated worker who has been infected with COVID–19, including those who are not experiencing symptoms of infection, will be permitted to spread the virus to others at the workplace, including unvaccinated coworkers.

Additionally, OSHA finds it necessary to require employers that do not implement a mandatory vaccination policy to ensure that unvaccinated workers wear face coverings in most situations when they are working near others. This reflects OSHA's recognition that regularly testing unvaccinated workers for COVID–19 will not be 100% effective in identifying infected workers before they enter the workplace. Most obviously, testing employees once a week will not prevent an unvaccinated

worker from exposing others at the workplace if the worker becomes infected and reports to the workplace in between their weekly tests. And, even if the rule required unvaccinated workers to be tested more frequently than once a week, infected persons may still be missed, particularly in areas with high community spread (Chin et al., September 9, 2020).

Accordingly, requiring unvaccinated workers to wear face coverings in most situations when they are working near others will further mitigate the potential for unvaccinated workers to spread the virus at the workplace. As discussed in the *Summary and Explanation* for paragraph (i) (Section VI.I. of this preamble), it is well-established that face coverings provide effective source control; that is, they largely prevent respiratory droplets emitted by the wearer of the face covering from spreading to others, and thus make it significantly less likely that the person wearing the mask will transmit the virus, if they are infected. Face coverings are also believed to provide the wearer some limited protection from exposure to the respiratory droplets of co-workers and others (e.g., customers) (CDC, May 7, 2021), but the principal benefit of face coverings is to significantly reduce the wearer's ability to spread the virus. By requiring unvaccinated workers to wear face coverings, this rule significantly reduces the likelihood that an infected unvaccinated worker who enters the workplace despite the testing requirements will spread the virus to others, including unvaccinated coworkers.

OSHA acknowledges that regularly testing unvaccinated workers for COVID–19 and requiring them to wear face coverings when they work near others is less protective of unvaccinated workers than simply requiring all workers to be vaccinated. To be sure, OSHA strongly prefers that employers adopt a mandatory vaccination policy, as vaccination is singularly effective at protecting workers from the severe consequences that can result from a COVID–19 infection. And, where employers do not adopt a mandatory vaccination policy, employers may also consider alternative feasible measures that would remove employees who remain unvaccinated from the scope of this ETS, such as increasing telework (see the *Summary and Explanation* for paragraph (b), Section VI.B. of this preamble). Nonetheless, as discussed above, OSHA has not imposed a strict vaccination mandate on all covered employees who work in the presence of others and not exclusively outdoors, given that the agency has never previously used its authority to strictly mandate vaccination, and the exigent and extraordinary circumstances driving this emergency rulemaking have not afforded OSHA a full opportunity to assess the potential ramifications of including a strict vaccination mandate in this rule. Given these circumstances, and employers' unique understanding of the compliance approaches that will best increase vaccination rates among their workforce, OSHA has designed a rule that preserves a limited degree of employer flexibility, and strongly encourages, but does not strictly require, vaccination. OSHA has requested comment in this ETS on whether a strict vaccination mandate would be appropriate and the agency will consider those comments as it determines how to proceed with this rulemaking.

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III. No Other Agency Action is Adequate To Protect Employees Against Grave Danger

OSHA's experience to date shows that the agency's existing tools are inadequate to meet the grave danger posed by COVID–19 to unvaccinated workers not covered by the Healthcare ETS. OSHA has determined that its existing standards, regulations, the OSH Act's General Duty Clause, and non-mandatory guidance will not adequately promote the most effective means to protect these workers: Vaccination. The agency has determined that this ETS is necessary to address these inadequacies. Multiple developments support this change in approach. First, large numbers of employees are continuing to contract COVID–19 and die. (See *Grave Danger*, Section III.A. of this preamble). Further, based on a thorough review of its existing approach to protecting employees from COVID–19 and the current state of the pandemic, OSHA finds that existing OSHA standards, regulations, the General Duty Clause, and non-mandatory guidance are not adequate to protect employees outside healthcare from COVID–19. The Preamble to the Healthcare ETS includes a detailed analysis demonstrating the inadequacy of existing tools in the healthcare industry. See 86 FR 32414–32423. In general, the same analysis applies here. The reasons existing tools were inadequate to protect healthcare workers apply in other industry sectors as well. The Healthcare ETS itself, while necessary to protect healthcare workers, of course applies only to that industry. Finally, the numerous guidance products published by other entities, such as CDC, are not adequate to protect employees because they are not enforceable; there is no penalty for noncompliance. 86 FR at 32415. Even as the CDC has increasingly recommended vaccination to protect from the dangers of transmission and severe illness related to the SARS–CoV–2 virus, vaccination rates remain uneven around the country. (CDC, September 9, 2021; Leonhardt, September 7, 2021; KFF, October 6, 2021; McPhillips and Cohen, May 19, 2021).

The need for this ETS is also reflected in the number of states and localities that have issued their own mandatory standards in recognition that OSHA's existing measures (including non-mandatory guidance, compliance assistance, and enforcement of existing standards) have failed to prevent the spread of the virus in workplaces. Additionally, as mentioned previously, other states have banned certain employers from implementing workplace vaccination mandates or from verifying an employee's vaccination status or from requiring face coverings. A national standard is necessary to establish clear requirements regarding vaccination, testing and face coverings that will protect employees in all states and preempt state or local ordinances that prevent employers from implementing necessary protections.

a. The Current Standards and Regulations Are Inadequate

In the Healthcare ETS, OSHA considered its enforcement efforts with regard to existing standards and regulations that OSHA had identified as potentially applicable to occupational exposure to SARS–CoV–2. OSHA's analysis in Section IV of the Healthcare ETS, 86 FR 32376, 32416–17 and hereby included in the record of this ETS,[18] is applicable here in considering the need for this ETS, which covers a much broader set of employers in all industries. There OSHA found that none of the existing OSHA standards could sufficiently abate the hazard posed by COVID–19 in healthcare settings. Here again OSHA concludes that the potentially applicable existing standards are insufficient to address the grave danger faced by workers covered by this ETS. None of the current standards, even if more rigorously enforced, can sufficiently address this cross-industry hazard of national proportions to abate the grave danger posed by COVID–19 or lead to the same benefits that this ETS will achieve. See *Asbestos Info. Ass'n/N. Am.* v. *Occupational Safety & Health Admin.*, 727 F.2d 415, 427 (5th Cir. 1984) (''[M]uch of the claimed benefit could be obtained simply by enforcing the current standard.'').

Through its enforcement guidance, OSHA identified a number of current standards and regulations that might apply when workers have occupational exposure to SARS–CoV–2, most of which are the same standards OSHA considered in the Healthcare ETS. (Updated Interim Enforcement Response Plan for Coronavirus Disease 2019 (COVID–19)) (OSHA, July 7, 2021). OSHA has also cited the Hazard communication standard (29 CFR 1910.1200) during COVID–19 investigations. Accordingly, a list of

[18] This adoption includes the citations in the referenced section of the Healthcare ETS, which are also included in the docket for this ETS.

potentially applicable standards and regulations follows:

- 29 CFR part 1904, Recording and Reporting Occupational Injuries and Illnesses. This regulation requires certain employers to keep records of work-related fatalities, injuries, and illnesses and report them to the government in specific circumstances.
- 29 CFR 1910.132, General requirements—Personal Protective Equipment (PPE). This standard requires that appropriate PPE, including PPE for eyes, face, head, and extremities, protective clothing, respiratory devices, and protective shields and barriers, be provided, used, and maintained in a sanitary and reliable condition.
- 29 CFR 1910.134, Respiratory protection. This standard requires that employers provide, and ensure the use of, appropriate respiratory protection when necessary to protect employee health.
- 29 CFR 1910.141, Sanitation. This standard applies to permanent places of employment and contains, among other requirements, general housekeeping and waste disposal requirements.
- 29 CFR 1910.145, Specification for accident prevention signs and tags. This standard requires the use of biological hazard signs and tags, in addition to other types of accident prevention signs and tags.
- 29 CFR Subpart U—COVID–19 Emergency Temporary Standard. The Healthcare ETS, promulgated on June 21, 2021 includes various controls (patient screening and management, respirators and other PPE, limiting exposure to aerosol-generating procedures, physical distancing, physical barriers, cleaning, disinfection, ventilation, health screening and medical management, access to vaccination, anti-retaliation provisions, and medical removal protection) to address the grave danger posed by COVID–19 to healthcare workers.
- 29 CFR 1910.1020, Access to employee exposure and medical records. This standard requires that employers provide employees and their designated representatives access to relevant exposure and medical records.
- 29 CFR 1910.1200, Hazard communication. This standard requires employers to keep Safety Data Sheets (SDS) for chemical hazards, provide SDSs to employees and their representatives when requested, and train employees about those hazards. The standard does not apply to biological hazards, but hazard communication becomes an issue for the SARS–CoV–2 virus when chemicals are used to disinfect surfaces.

OSHA again finds that none of these existing standards provide for the types of workplace controls that are necessary to combat the grave danger addressed by this ETS. First, none of the listed potentially applicable standards require vaccination against SARS–CoV–2, the most efficient and effective control to combat the grave danger posed by the virus. (The Bloodborne Pathogen Standard requires that the hepatitis B vaccine be made available to certain employees, but that is not that is not relevant here, since the hepatitis vaccine provides no protection against COVID–19). Nor are the additional safety measures included in this ETS—vaccination verification, screening testing, face coverings, and medical removal of COVID–19 positive workers— required by existing standards other than OSHA's Healthcare ETS (covering employees exempted from this new ETS while the Healthcare ETS is in effect).

Second, because existing standards do not contain provisions specifically targeted at the COVID–19 hazard, it may be difficult for employers and employees to determine what particular COVID–19 safety measures are required by existing standards, or how the separate standards are expected to work together as applied to COVID–19. An ETS that contains provisions specifically addressing COVID–19 hazards in covered workplaces will provide clear instructions. More certainty will lead to more compliance, and more compliance will lead to improved protection of employees covered by this standard.

Third, requirements in some standards may be appropriate for other situations but simply do not contemplate COVID–19 and fail to address important aspects of the hazard. For example, the general sanitation standard requires employers to provide warm water, soap, and towels that can be used in hand washing, but does not require disinfection or provision of hand sanitizer where handwashing facilities cannot be made readily available. See 86 FR 32417. Although the sanitation standard might appear at first glance to be relevant here, it simply does not require the types of controls that would, even if more rigorously enforced, sufficiently reduce the threat of COVID–19 in the workplace. As such, OSHA affirms its previous determination that some of the above-listed standards—including the sanitation standard—are in practice too difficult to apply to the COVID–19 hazard and have never been cited in COVID enforcement. 86 FR 32416.

Fourth, existing recordkeeping and reporting regulations do not adequately allow the employer or the agency to assess the full scope of COVID–19 workplace exposures and protection. OSHA's general recordkeeping regulations were not written with the nature of COVID–19 transmission or illness in mind. In order to adequately understand and thereby control the spread of COVID–19 in the workforce, it is critical that the employer has records of employees' vaccination status, and of the testing undergone by employees who do not receive vaccination, and that it knows of all cases of COVID–19 occurring among employees. However, such information is outside of the scope of OSHA's existing recordkeeping requirements, which are limited to injuries or illnesses that the employer knows to be work-related.

Moreover, existing reporting regulations do not adequately ensure that OSHA has the full picture of the impact of COVID–19 because those regulations only require employers to report in-patient hospitalizations that occur within 24 hours of the work-related incident and to report fatalities that occur within thirty days of the work-related incident. 86 FR at 32417. Many COVID–19 infections will not result in hospitalization or death until well after these limited reporting periods. Under existing regulations, such cases are not required to be reported to OSHA, which limits the agency's ability to fully understand the impact of COVID–19 on the workforce. 86 FR 32417. This ETS includes a provision, paragraph (k), that removes the time limitation on reporting for COVID–19 cases.

In conclusion, OSHA's experience has demonstrated that existing standards and regulations are inadequate to address the current COVID–19 hazard.

b. The General Duty Clause Is Inadequate To Meet the Current Crisis

Section 5(a)(1) of the OSH Act, or the General Duty Clause, provides the general mandate that each employer ''furnish to each of [its] employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to [its] employees.'' 29 U.S.C. 654(a)(1). For General Duty Clause citations to be upheld, OSHA must demonstrate elements of proof that are supplementary to, and can be more difficult to show than, the elements of proof required for violations of specific standards, where a hazard is presumed. Specifically, to prove a violation of the General Duty Clause, OSHA needs to

establish—in each individual case—that: (1) An activity or condition in the employer's workplace presented a hazard to an employee; (2) the hazard was recognized; (3) the hazard was causing or was likely to cause death or serious physical harm; and (4) feasible means to eliminate or materially reduce the hazard existed. *BHC Nw. Psychiatric Hosp., LLC* v. *Sec'y of Labor*, 951 F.3d 558, 563 (D.C. Cir. 2020). OSHA often relies on the General Duty Clause to fill gaps where specific standards do not address a hazard and OSHA enforces it through case-by-case adjudicative proceedings. See *United States* v. *Strum*, 84 F.3d 1, 5 (1st Cir. 1996).

OSHA has previously found the General Duty Clause to be inadequate to protect employees from dangers posed by infectious agents. In promulgating the bloodborne pathogens standard, OSHA explained that enforcement under the General Duty Clause was insufficient to protect employees from the serious hazards those pathogens present. 56 FR 64007 (December 6, 1991). In the recently promulgated Healthcare ETS, OSHA found that the General Duty Clause was insufficient to protect healthcare workers from the grave danger they faced as well. 86 FR 32418. While OSHA initially attempted to use the General Duty Clause to protect employees across all industries from COVID–19-related hazards, OSHA's experience has demonstrated that the Clause is grossly inadequate to protect employees covered by this ETS from the grave danger posed by COVID–19 in the workplace. As explained more fully below, OSHA finds this ETS is necessary to protect employees from the hazards of COVID–19.

As an initial matter, the General Duty Clause does not provide employers with specific requirements to follow or a roadmap for implementing appropriate abatement measures. The ETS, however, provides a clear statement of what OSHA expects employers to do to protect workers, thus facilitating better compliance. The General Duty Clause is so named because it imposes a *general* duty to keep the workplace free of recognized serious hazards; the ETS, in contrast, lays out clear requirements for employers to implement vaccination policies including vaccination verification, support for employee vaccination, screening testing and face coverings for unvaccinated workers, and medical removal of COVID–19 positive employees. Conveying obligations as clearly and specifically as possible makes it much more likely that employers will comply with those obligations and thereby protect workers from COVID–19 hazards. See, e.g., *Integra Health Mgmt., Inc.*, 2019 WL 1142920, at *7 n.10 (No. 13–1124, 2019) (noting that standards ''give clear notice of what is required of the regulated community''); 56 FR 64007 (''because the standard is much more specific than the current requirements [general standards and the general duty clause], employers and employees are given more guidance in carrying out the goal of reducing the risks of occupational exposure to bloodborne pathogens'').

Moreover, several characteristics of General Duty Clause enforcement actions make them an inadequate means to address hazards associated with COVID–19. First, it would be virtually impossible for OSHA to require and enforce the most important worker-protective elements of the ETS (such as vaccination and testing) under the General Duty Clause. Second, OSHA's burden of proof for establishing a General Duty Clause violation is heavier than for standards violations. Third, promulgating an ETS will enable OSHA to issue more meaningful penalties for willful and egregious violations, thus creating effective deterrence against employers who intentionally disregard their obligations under the Act or demonstrate plain indifference to employee safety. As discussed in more detail below, all of these considerations demonstrate OSHA's need to promulgate this ETS in order to protect unvaccinated workers covered by this standard from hazards posed by COVID–19.

The General Duty Clause is ill-suited to requiring employers to adopt vaccination and testing policies, like those required by the ETS

Because the General Duty Clause requires OSHA to establish the existence and feasibility of abatement measures that can **materially reduce** a hazard, it is difficult for OSHA to use the clause to require specific control measures where an employer is doing something, but not what the Secretary has determined is needed to fully address the serious hazard. See, e.g., *Waldon Health Care Center*, 16 BNA OSHC 1052, 1993 WL 119662 at * (No. 89–2804, 1993) (vacating OSHA citation requiring pre-exposure hepatitis B vaccination under General Duty Clause by finding that although vaccination would more fully reduce the hazard, the employer's chosen means of abatement were sufficient); *Brown & Root, Inc., Power Plant Div.*, 8 BNA OSHC 2140, 1980 WL 10668 at *5 (No. 76–1296, 1980) (''[T]he employer may defend against a section 5(a)(1) citation by asserting that it was using a method of abatement other than the one suggested by the Secretary.'').

Further, even where OSHA establishes a violation of the General Duty Clause, the employer is under no obligation to implement the feasible means of abatement proven by OSHA as part of its prima facie case. *Cyrus Mines Corp.*, 11 OSH Cas. (BNA) 1063, 1982 WL 22717, at *4 (No. 76–616, 1983) (''[The employer] is not required to adopt the abatement method suggested by the Secretary, even one found feasible by the Commission; it may satisfy its duty to comply with the standard by using any feasible method that is appropriate to abate the violation.''); *Brown & Root, Inc., Power Plant Div.*, 1980 WL 10668 at *5. Thus, even in cases where OSHA prevails, the employer need not necessarily implement the specific abatement measure(s) OSHA established would materially reduce the hazard. The employer could select alternative controls and then it would be up to OSHA, if it wished to cite the employer again, to establish that the recognized hazard continued to exist and that its preferred controls could materially reduce the hazard even further.

Given the severity and pervasiveness of the COVID–19 hazard, OSHA has determined that the specific abatement measures provided in this ETS are necessary to protect workers from grave danger. Under the General Duty Clause alone, it would be nearly impossible to require employers to provide these specific measures, and even then, it could only be on a case-by-case enforcement basis. Considering the magnitude and ubiquity of the danger that SARS–CoV–2 poses to workers across the country, the case-by-case adjudicatory regime set up through the General Duty Clause is simply not adequate to combat the risk of severe illness and death caused by the virus.

General Duty Clause Citations Impose a Heavy Litigation Burden on OSHA

Under the General Duty Clause OSHA must prove that there is a recognized hazard, i.e., a workplace condition or practice to which employees are exposed, creating the potential for death or serious physical harm to employees. See *SeaWorld of Florida LLC* v. *Perez*, 748 F.3d 1202, 1207 (D.C. Cir. 2014); *Integra Health Management,* 2019 WL 1142920, at *5. Whether a particular workplace condition or practice is a ''recognized hazard'' under the General Duty Clause is a question of fact that must be decided in each individual case. See *SeaWorld of Florida LLC*, 748 F.3d at 1208. In the case of a COVID–19-related citation, this means showing

not just that the virus is a hazard as a general matter—a fairly indisputable point—but also that the specific conditions in the cited workplace, such as unvaccinated, unmasked employees working in close proximity to other employees for extended periods, create a COVID–19-related hazard.

In contrast, an OSHA standard that requires or prohibits specific conditions or practices establishes the existence of a hazard. See *Harry C. Crooker & Sons, Inc.* v. *Occupational Safety & Health Rev. Comm'n*, 537 F.3d 79, 85 (1st Cir. 2008); *Bunge Corp.* v. *Sec'y of Labor*, 638 F.2d 831, 834 (5th Cir. 1981). Thus, in enforcement proceedings under OSHA standards, as opposed to the General Duty Clause, ''the Secretary need not prove that the violative conditions are actually hazardous.'' *Modern Drop Forge Co.* v. *Sec'y of Labor*, 683 F.2d 1105, 1114 (7th Cir. 1982). With OSHA's finding that the hazard of exposure to COVID–19 can exist for unvaccinated workers in all covered workplaces (see *Grave Danger*, Section III.A. of this preamble), the ETS will eliminate the burden to repeatedly prove, workplace by workplace, the existence of a COVID–19 hazard under the General Duty Clause.

One of the most significant advantages to standards like the ETS that establish the existence of the hazard at the rulemaking stage is that the Secretary can require specific abatement measures without having to prove that a specific cited workplace is already hazardous.[19] In contrast, as discussed above, under the General Duty Clause the Secretary cannot require abatement before proving in the enforcement proceeding that an existing condition at the workplace is hazardous. For example, in a challenge to OSHA's Grain Handling Standard, which was promulgated in part to protect employees from the risk of fire and explosion from accumulations of grain dust, the Fifth Circuit acknowledged OSHA's inability to effectively protect employees from these hazards under the General Duty Clause in upholding, in large part, the standard. See *Nat'l Grain & Feed Ass'n* v. *Occupational Safety & Health Admin.*, 866 F.2d 717, 721 (5th Cir. 1988) (noting Secretary's difficulty in proving explosion hazards of grain handling under General Duty Clause). Although OSHA had attempted to address fire and explosion hazards in the grain handling industry under the General Duty Clause, ''employers generally were successful in arguing that OSHA had not proved that the specific condition cited could cause a fire or explosion.'' Id. at 721 & n.6 (citing cases holding that OSHA failed to establish a fire or explosion hazard under the General Duty Clause). The Grain Handling Standard, in contrast, established specific limits on accumulations of grain dust based on its combustible and explosive nature, and the standard allowed OSHA to cite employers for exceeding those limits without the need to prove at the enforcement stage that each cited accumulation was likely to cause a fire or explosion. See id. at 725–26.

The same logic applies to COVID–19 hazards. Given OSHA's burden under the General Duty Clause to prove that conditions at the cited workplace are hazardous, it is difficult for OSHA to ensure necessary abatement *before* individual employee lives and health are unnecessarily endangered by exposure to COVID–19, despite widespread evidence of the grave danger posed by worker exposure to COVID–19. Indeed, despite publishing a voluminous collection of COVID–19 guidance online and receiving and investigating thousands of complaints, OSHA did not believe it could justify the issuance of more than 20 COVID–19 related General Duty Clause citations over the entire span of the pandemic so far, because of the quantum of proof the Secretary must amass under the General Duty Clause. Unlike enforcement under the General Duty Clause, this ETS allows OSHA to cite employers for each protective requirement they fail to implement without the need to wait for employee infection or death to prove in an enforcement proceeding that the particular cited workplace was hazardous without that particular measure in place. Thus, this ETS, which covers millions of workers nation-wide, is significantly preferable to the General Duty Clause with respect to such a highly transmissible virus because the inability to prevent a single exposure can quickly result in an exponential increase in exposures and illnesses or fatalities even at a single worksite.

An additional limitation of the General Duty Clause is that proving that there are feasible means to materially reduce a recognized hazard typically requires testimony from an expert witness in each separate case, which limits OSHA's ability to prosecute these cases as broadly as needed to protect workers, in light of the expense involved. See, e.g., *Integra Health Management*, 2019 WL 1142920, at *13 (requiring expert witness to prove proposed abatement measures would materially reduce hazard). In contrast, where an OSHA standard specifies the means of compliance, the agency has already made the necessary technical determinations in the rulemaking and therefore does not need to establish feasibility of compliance as part of its *prima facie* case in an enforcement proceeding. See, e.g., *A.J. McNulty & Co.* v. *Sec'y of Labor*, 283 F.3d 328, 334 (D.C. Cir. 2002); *S. Colorado Prestress Co.* v. *Occupational Safety & Health Rev. Comm'n*, 586 F.2d 1342, 1351 (10th Cir. 1978). Preventing the initial exposure and protecting as many workers as quickly as possible is especially critical in the context of COVID–19 because, as explained in Grave Danger, Section III.A. of this preamble, it can spread so easily in workplaces.

The ETS will also permit OSHA to achieve meaningful deterrence when necessary to address willful or egregious failures to protect employees against the COVID–19 hazard

As described above, in contrast to the broad language of the General Duty Clause, this ETS will prescribe specific measures employers covered by this standard must implement. This specificity will make it easier for OSHA to determine whether an employer has intentionally disregarded its obligations or exhibited a plain indifference to employee safety or health. In such instances, OSHA can classify the citations as ''willful,'' allowing it to propose higher penalties, with increased deterrent effects. In promulgating the Healthcare ETS, OSHA noted that early in the pandemic, shifting guidance on the safety measures employers should take to protect their employees from COVID–19 created ambiguity regarding employers' specific obligations. Thus, OSHA could not readily determine whether a particular employer had ''intentionally'' disregarded obligations that were not yet clear. And, even as the guidance began to stabilize, OSHA's ability to determine ''intentional disregard'' or ''plain indifference'' was difficult, for example, when an employer took some steps address the COVID–19 hazard. 86 FR 32420. The Healthcare ETS largely resolved this issue for employers covered by that standard, by laying out clearly what parameters to put in place to protect healthcare workers. However, this general challenge persists in OSHA's

[19] ''The Act does not wait for an employee to die or become injured. It authorizes the promulgation of health and safety standards and the issuance of citations in the hope that these will act to prevent deaths and injuries from ever occurring.'' *Whirlpool Corp,* v. *Marshall,* 445 U.S. 1, 12 (1980); see also *Arkansas-Best Freight Sys., Inc.* v. *Occupational Safety & Health Rev. Comm'n*, 529 F.2d 649, 653 (8th Cir. 1976) (noting that the ''[OSH] Act is intended to prevent the first injury'').

attempts at enforcement in other industries.

Further, OSHA has adopted its ''egregious violation'' policy to impose sufficiently large penalties that achieve appropriate deterrence against bad actor employers who willfully disregard their obligation to protect their employees when certain aggravating circumstances are present, such as a large number of injuries or illnesses, bad faith, or an extensive history of noncompliance (OSHA Directive CPL 02–00–080 (October 21, 1990)). Its purpose is to increase the deterrent impact of OSHA's enforcement activity. This policy utilizes OSHA's authority to issue a separate penalty for each instance of noncompliance with an OSHA standard, such as each employee lacking the same required protections, or each workstation lacking the same required controls. It can be more difficult to use this policy under the General Duty Clause because the Fifth Circuit and the Occupational Safety and Health Review Commission have held that, under the General Duty Clause, OSHA may only cite a hazardous condition once, regardless of its scope or the number of workers affected. *Reich* v. *Arcadian Corp.*, 110 F.3d 1192, 1199 (5th Cir. 1997). Thus, even where OSHA finds that an employer willfully failed to protect a large number of employees from a COVID–19 hazard, OSHA might not be able to cite the employer on a per-instance basis for failing to protect each of its employees. The provisions of this ETS have been intentionally drafted to make clear OSHA's authority to separately cite employers for each instance of the employer's failure to protect employees and for each affected employee, where appropriate.

By providing needed clarity, the ETS will facilitate ''willful'' and ''egregious'' determinations that are critical enforcement tools OSHA can use to adequately address violations by employers who have shown a conscious disregard for the health and safety of their workers in response to the pandemic. Without the necessary clarity, OSHA has been limited in its ability to impose penalties high enough to motivate the very large employers who are unlikely to be deterred by penalty assessments of tens of thousands of dollars, but whose noncompliance can endanger thousands of workers. Indeed, OSHA has only been able to issue two COVID–19-related ''willful'' citations and no ''egregious'' citations since the start of the pandemic because of the challenges described above.

For all of the reasons described above, and after over a year of attempting to use the General Duty Clause to address this widespread hazard, OSHA finds that the General Duty Clause is not an adequate enforcement tool to protect employees covered by this standard from the grave danger posed by COVID–19.

c. OSHA and Other Entity Guidance Is Insufficient

OSHA has issued numerous non-mandatory guidance products to advise employers on how to protect workers from SARS–CoV–2 infection (see *https://www.osha.gov/coronavirus*). Even the most comprehensive guidance makes clear, as it must, that the guidance itself imposes no new legal obligations, and that its recommendations are ''advisory in nature.'' (See OSHA's online guidance, Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID–19 in the Workplace (OSHA, Updated August 13, 2021); and OSHA's earlier 35-page booklet, Guidance on Preparing Workplaces for COVID–19, (OSHA, March 9, 2020)). This guidance, as well as guidance products issued by other government agencies and organizations, including the CDC, the Centers for Medicare & Medicaid Services (CMS), the Institute of Medicine (IOM), and the World Health Organization (WHO), help protect employees to the extent that employers voluntarily choose to implement the practices they recommend. Unfortunately, OSHA's experience and the continued spread of COVID–19 throughout the country shows that does not happen consistently or rigorously enough, resulting in inadequate protection for employees. For example, the CDC has strongly recommended vaccination since vaccines became widely available earlier in the year, but many employees have yet to take this simple step, which would protect themselves and their co-workers from the danger of COVID–19.

As documented in numerous peer-reviewed scientific publications, CDC, IOM, and WHO have recognized a lack of compliance with non-mandatory recommended infection-control practices (Siegel et al., 2007; IOM, 2009; WHO, 2009). As noted in the preamble to the Healthcare ETS, OSHA was aware of these findings when it previously concluded that an ETS was not necessary, but at the time of that conclusion, the agency erroneously believed that it would be able to effectively use the non-mandatory guidance as a basis for establishing the mandatory requirements of the General Duty Clause, and informing employers of their compliance obligations under existing standards. 86 FR 32421. As explained above, that has not proven to be an effective strategy. Moreover, when OSHA made its initial necessity determination at the beginning of the pandemic, it made an assumption that given the unprecedented nature of the COVID–19 pandemic, there would be an unusual level of widespread voluntary compliance by the regulated community with COVID–19-related safety guidelines. (See, *e.g.,* DOL, May 29, 2020 at 20 (observing that ''[n]ever in the last century have the American people been as mindful, wary, and cautious about a health risk as they are now with respect to COVID–19,'' and that many ''protective measures are being implemented voluntarily, as reflected in a plethora of industry guidelines, company-specific plans, and other sources'')).

Since that time, however, developments have led OSHA to conclude that the same uneven compliance documented by CDC, IOM, and WHO is also occurring for the COVID–19 guidance issued by OSHA and other agencies. For example, rising ''COVID fatigue'' or ''pandemic fatigue'' has been reported for nearly a year already—*i.e.,* a decrease in voluntary use of COVID–19 mitigation measures over time (Meichtry et al., October 26, 2020; Silva and Martin, November 14, 2020; Belanger and Leander, December 9, 2020; Millard, February 18, 2021). Other reasons that people have not followed COVID–19 guidance include fear of financial loss; skepticism about the danger posed by COVID–19; and even a simple human tendency, called ''psychological reactance,'' to resist curbs on personal freedoms, *i.e.,* an urge to do the opposite of what somebody tells you to do (Belanger and Leander, December 9, 2020; Markman, April 20, 2020). OSHA is seeing evidence of these trends in its COVID–19 enforcement. For example, although OSHA has issued guidance since the spring of 2020 encouraging the use of physical distancing and barriers as a means of protecting employees at fixed work locations, there have been a number of news reports indicating that employers ignore that guidance (Romo, November 19, 2020; Richards, May 5, 2020; Lynch, July 9, 2020). This was evidenced by a cross-sectional study performed from late summer to early fall of 2020 in New York and New Jersey that found non-compliance and widespread inconsistencies in COVID–19 response programs (Koshy et al., February 4, 2021). Indeed, OSHA continues to receive complaints and referrals attesting to such workplace practices.

(OSHA, October 17, 2021). Worse, some employers must now deal with employees who not only have yet to be vaccinated but compound the danger by hiding their unvaccinated status and declining to wear source protection that would identify them as unvaccinated, even though it could provide some protection to their coworkers, in workplaces where there is a stigma attached to being unvaccinated. (Ember and Murphy Marcos, August 7, 2021). This ETS contains notification and vaccine verification requirements that address these avoidant behaviors and mitigate the hazard of undisclosed exposure and transmission (see the *Summary and Explanation* for paragraphs (e), (g), and (h), Sections VI.E., VI.G., and VI.H. of this preamble).

OSHA's more recent guidance update encourages employers to facilitate employee vaccination by providing paid time off and encourages testing and masks for unvaccinated workers. However, as discussed previously, vaccination rates remain inconsistent across the country and have slowed significantly since the spring of 2021. And infection rates remain high, especially among the unvaccinated. It is clear, as discussed previously, that voluntary self-regulation by employers will not sufficiently reduce the danger that COVID–19 poses in workplaces covered by this standard. As noted in the White House Report on vaccination requirements released on October 7, at this time only 25% of businesses have vaccine mandates in place (White House, October 7, 2021). Since this ETS and other federal efforts to require vaccination were announced more private and public sector institutions have begun to prepare to implement vaccination requirements, further demonstrating the need for this rule as an impetus for employer action (White House, October 7, 2021).

The high number of COVID–19-related complaints and reports that OSHA continues to receive on a regular basis suggests a lack of widespread compliance with existing voluntary guidance: From March 2020 to October 2021, OSHA has continued to receive hundreds of COVID–19-related complaints every month, including over 400 complaints during the month of August 2021, and over 450 complaints to date in the month of September (OSHA, October 11, 2021). And, as of October 17, OSHA has received 223 additional COVID–19-related complaints. (OSHA, October 17, 2021). If guidance were followed more strictly, or if there were enough voluntary compliance with steps to prevent illness, OSHA would expect to see a significant reduction in COVID–19-related complaints from employees.

The dramatic increases in the percentage of the population that contracted the virus during the summer of 2021 indicates a continued risk of COVID–19 transmission in workplace settings (for more information on the prevalence of COVID–19 see *Grave Danger*, Section III.A. of this preamble) despite OSHA's publication of numerous specific and comprehensive guidance documents. OSHA has found that neither reliance on voluntary action by employers nor OSHA non-mandatory guidance is an adequate substitute for *specific, mandatory* workplace standards at the federal level. *Public Citizen* v. *Auchter*, 702 F.2d 1150 at 1153 (voluntary action by employers ''alerted and responsive'' to new health data is not an adequate substitute for government action).

d. A Uniform Nationwide Response to the Pandemic Is Necessary To Protect Workers

As the pandemic has continued in the United States, there has been increasing recognition of the need for a more consistent national approach (GAO, September, 2020; Budryk, November 17, 2020; Horsley, May 1, 2020; DOL OIG, February 25, 2021). Many employers have advised OSHA that they would welcome a nationwide ETS. For example, in its October 9, 2020 petition for a COVID–19 ETS, ORCHSE Strategies, LLC explained that it is ''imperative'' that OSHA issue an ETS to provide employers one standardized set of requirements to address safety and health for their workers (ORCHSE, October 9, 2020). This group of prominent business representatives explained that an ETS would eliminate confusion and unnecessary burden on workplaces that are struggling to understand how best to protect their employees in the face of confusing and differing requirements across states and localities.

The lack of a national standard on this hazard has led to increasing imbalance in state and local regulation, a problem that OSHA already identified as concerning in its Healthcare ETS. See 86 FR 32413 (''The resulting patchwork of state and local regulations led to inadequate and varying levels of protection for workers across the country, and has caused problems for many employees and businesses.'') Since the Healthcare ETS was published, states and localities have taken increasingly more divergent approaches to COVID–19 vaccination, vaccination verification, screening testing, and the use of face coverings in the workplace. Currently, the spectrum ranges from states and localities requiring vaccine mandates and face coverings to states prohibiting or restricting them, with many states falling somewhere in between. Due to uneven approaches to vaccination across the country, states with the lowest rates of vaccination have COVID–19 infection rates four times as high as in states with the highest vaccine rates. (Leonhardt, September 7, 2021). Given that thousands of working age people continue to be infected with COVID–19 each week, many of whom will become hospitalized or die, OSHA recognizes that a patchwork approach to worker safety has not been successful in mitigating this infectious disease outbreak (CDC, October 18, 2021—Cases, By Age). It has become clear that a Federal standard, by way of this ETS, is necessary to provide clear and consistent protection to employees across the country. As explained in *Pertinent Legal Authority* (Section II. of this preamble) and the *Summary and Explanation* for paragraph (a) (Section VI.A. of this preamble), OSHA has the authority to comprehensively address the issue(s) described in this ETS, and the standard is intended to preempt conflicting state and local laws.

In sum, based on its enforcement experience during the pandemic to date, OSHA concludes that continued reliance on existing standards and regulations, the General Duty Clause, and guidance, in lieu of an ETS, is not adequate to protect unvaccinated employees from the grave danger of being infected by, and suffering death or serious health consequences from, COVID–19.

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IV. Conclusion

This pandemic continues to take a massive toll on American society, and addressing it requires a comprehensive national response. This ETS is part of that response. OSHA shares the nation's hope for the promise of recovery created by the vaccines. But in the meantime, it recognizes that we have not yet succeeded in defeating the virus, and that many workers across the country are in grave danger. Therefore, this ETS, with mitigation measures emphasizing worker vaccination, is necessary. Although OSHA finds it necessary to institute specific mitigation measures for the immediate future, the agency can adjust as conditions change. Even after issuing an ETS, OSHA retains the flexibility to update the ETS to adjust to the subsequent evolution of CDC workplace guidance. This ETS addresses (and incorporates as a main component) the major development in infection control over the last year—the development and growing implementation of COVID–19 vaccines. Going forward, further developments can be addressed through OSHA's

authority to modify the ETS if needed, or to terminate it entirely if vaccination and other efforts end the current emergency. However, at this point in time, the available evidence indicates that the ETS is necessary to protect unvaccinated employees across the country from the grave danger of COVID–19.

IV. Feasibility

A. Technological Feasibility

This section presents an overview of the technological feasibility assessment for OSHA's Emergency Temporary Standard (ETS) for COVID–19 that requires all employers with 100 or more employees to ensure that all employees are fully vaccinated unless they implement a policy requiring employees to undergo testing for COVID–19 at least once every seven days and wear face coverings.

Technological feasibility has been interpreted broadly to mean ''capable of being done'' (*Am. Textile Mfrs. Inst.* v. *Donovan*, 452 U.S. 490, 509–510 (1981)). A standard is technologically feasible if the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed, i.e., technology that ''looms on today's horizon'' (*United Steelworkers of Am., AFL–CIO–CLC* v. *Marshall*, 647 F.2d 1189, 1272 (D.C. Cir. 1980) (*Lead I*)); *Amer. Iron & Steel Inst.* v. *OSHA*, 939 F.2d 975, 980 (D.C. Cir. 1991) (*Lead II*); *American Iron and Steel Inst.* v. *OSHA*, 577 F.2d 825 (3d Cir. 1978)). Courts have also interpreted technological feasibility to mean that a typical firm in each affected industry or application group will reasonably be able to implement the requirements of the standard in most operations most of the time (see *Public Citizen* v. *OSHA*, 557 F.3d 165 (3d Cir. 2009); *Lead I*, 647 F.2d at 1272; *Lead II*, 939 F.2d at 990).

OSHA issued an ETS in June 2021 to protect healthcare and healthcare support employees in covered healthcare settings from exposure to SARS–CoV–2. See 86 FR 32376 (June 21, 2021) (Healthcare ETS). OSHA found the requirements in that ETS to be technologically feasible, including a requirement for employers to pay for vaccination of employees that is very similar to the requirement in this new ETS. OSHA's finding that the Healthcare ETS was technologically feasible was primarily based on available evidence showing that most healthcare employers, and employers across all industry sectors, had already implemented, or were in process of implementing, procedures similar to those required by the Healthcare ETS. Similarly, OSHA's feasibility findings for this ETS are based on evidence that vaccination and testing policies, along with the use of face coverings consistent with recommendations from the CDC, have been implemented in multiple industry sectors as testing and vaccinations were made more widely available during the course of the pandemic.

As discussed in *Summary and Explanation* (Section VI. of this preamble), this ETS for vaccination and testing applies to all employers with 100 or more employees, except as noted here. It does not apply to workplaces covered under the Safer Federal Workforce Task Force COVID–19 Workplace Safety: Guidance for Federal Contractors and Subcontractors or settings where any employee provides healthcare services or healthcare support services when subject to the requirements of the Healthcare ETS (29 CFR 1910.502). It also does not apply to employees who do not report to a workplace where other individuals such as coworkers or customers are present, employees while they are working from home, or employees who work exclusively outdoors.

As noted above, OSHA has the legal duty to demonstrate that the average employer covered by this ETS can comply with that standard in most operations most of the time. This legal analysis is therefore focused solely on whether employers with 100 or more employees can comply with the standard. OSHA's rationale for that scope threshold of 100 or more employees is explained in the *Summary and Explanation* for paragraph (b), Section VI.B. of this preamble.

As discussed below, OSHA finds no technological feasibility barriers related to compliance with the requirements in the ETS. These requirements include establishing and implementing a written mandatory COVID–19 vaccination policy or alternative policy requiring testing and face coverings; determining employee vaccination status; supporting employee vaccination by providing paid time for vaccination and time off for recovery; ensuring that employees who are not fully vaccinated are tested for COVID–19 at least once every seven days and wear face coverings; and recordkeeping for employee vaccination status and testing.

OSHA reviewed numerous large-scale employer surveys and vaccination and testing policies developed by employers, public health organizations, trade association, and local, state, and federal governmental bodies. While OSHA discusses several examples of these plans and policies below,[20] OSHA's feasibility determination is based on all evidence in the rulemaking record. The majority of the survey data and other publicly available material that OSHA reviewed pertains to large employers with 100 or more employees.

Additionally, OSHA thoroughly reviewed current and future projections of the availability of COVID–19 tests, testing supplies, and laboratory capacity. Based on a review of vaccination and testing policies among large employers, OSHA has determined that most employers covered by this standard across a wide range of industries have either already implemented vaccination and testing programs and require unvaccinated employees to wear face coverings, or are capable of implementing programs that comply with the requirements in the ETS most of the time. OSHA therefore finds that the standard is technologically feasible.

I. Employer Policy on Vaccination

Paragraph (d)(1) of the ETS requires each covered employer to establish and implement a written mandatory vaccination policy unless the employer adopts an alternative policy requiring COVID–19 testing and face coverings for unvaccinated employees, which is discussed later. To meet the definition of ''mandatory vaccination policy'' under paragraph (c), the policy must require: Vaccination of all employees, including all new employees as soon as practicable, other than those employees (1) for whom a vaccine is medically contraindicated, (2) for whom medical necessity requires a delay in vaccination, or (3) those legally entitled to a reasonable accommodation under federal civil rights laws because they have a disability or sincerely-held religious beliefs, practices, or observances that conflict with the vaccination requirement.

OSHA requires employers to implement a mandatory vaccination requirement, but provides an exemption for an alternative policy that allows employees to choose either to be fully vaccinated or to be regularly tested and wear a face covering. This compliance options mean that the ETS is

[20] While OSHA references several employers' policies, this is not intended to serve as an endorsement of those plans or an indication that those plans comply with the ETS. Rather, the plans and best practice documents show that developing and implementing policies to address employee COVID–19 vaccination in various workplaces is capable of being done in a variety of industries, and therefore, compliance with the ETS is technologically feasible.

technologically feasible if employers across various industries are capable of implementing either policy, but nevertheless OSHA analyzes both employer policy options to demonstrate that there are no significant technological barriers to either approach.

OSHA reviewed several large-scale employer surveys related to vaccination policies across the country covering a wide range of industry sectors. Surveys conducted by Arizona State University (ASU) and the World Economic Forum (WEF), called *COVID–19 Workplace Commons—Keeping Workers Well*, show that most employers already have some type of vaccination policy, with more than 60 percent of surveyed employers requiring vaccinations for some or all employees. These survey results further support OSHA's determination that the vaccination policy requirement is feasible.

The ASU WEF workplace COVID–19 surveys collected information from employers across industry sectors about their response to the COVID–19 pandemic. The results and responses from more than 1,400 companies are publicly available through the ASU College of Health Solutions web page COVID–19 Diagnostics Commons (ASU, October 5, 2021). Case studies from employers are also available within the interactive dashboard on that web page. The surveys consisted of numerous questions about workplace pandemic response, including questions related to vaccination policies and testing unvaccinated employees.

The most recent COVID–19 survey data was collected between August 2, 2021 and August 20, 2021 and reported in September 2021 (accessible through the COVID–19 Workplace Commons). More than 1,400 companies operating 1143 facilities in 23 industry sectors were part of the survey, the majority of which are companies of the size covered by the ETS. Ninety percent of facilities surveyed had 100 or more employees at their facilities, and 56% had more than 100 but less than 1,000 employees at their facilities. The industry sectors surveyed include: Technology and software; business and professional services; manufacturing; construction; healthcare, hospitals, and clinics; retail stores; retail food stores; consumer retail service; energy and utilities; nonprofit organizations; education (colleges and universities); education (pre-K to 12); real estate and property management; agriculture and food production; healthcare services; media and entertainment; government and quasi-public; biotech, pharmaceuticals, and diagnostics; restaurants and food service; hotels and casinos; transportation, distribution, and logistics; consumer transportation; and recreation (ASU WEF, September 2021).

The survey responses related to vaccination policies support OSHA's determination that it is feasible for covered employers to implement mandatory COVID–19 vaccination policies. The survey results showed that 45% of employers surveyed require all employees to be vaccinated against COVID–19, and an additional 16% require some of its employees to be vaccinated against COVID–19. (ASU WEF, September 2021). Only three percent of employers surveyed did not have a vaccination policy at the time (ASU WEF, September 2021). While this survey covers a wide range of industries it may not represent the percentage of companies implementing mandatory vaccination policies in general populations but for the feasibility purposes it demonstrates that it has and can be done.

OSHA also reviewed slightly older survey data, which, even though it shows somewhat lower rates of employer vaccination mandates, still supports OSHA's finding that such vaccination polices are feasible. In late June 2021, the National Safety Council (NSC) conducted three national surveys, one organizational and two workforce, of private companies, nonprofits, legal experts, public health professionals, medical professionals and government agencies that have addressed workforce COVID–19 vaccinations based on best practices and proven workplace safety strategies. The survey results show that many employers and organizations are currently requiring employees to be vaccinated.

The three surveys were distributed to 300 employers and organizations across the country and from a wide range of industries to collect data on pandemic response, including implementation of COVID–19 vaccine policies and testing among their workforce. Of the employers and organizations surveyed in June 2021, the NSC found that 20% were implementing some form of a worker vaccination requirement. While OSHA believes that the ASU WEF surveys (which included more employers and are more recent) are better indicators of current employer vaccination policies, the NSC surveys also support the feasibility of employer vaccination mandates (NSC, September 2021)

The NSC, in partnership with the Health Action Alliance (HAA) and the Centers for Disease Control and Prevention (CDC), have developed a multifaceted, comprehensive effort called SAFER, aimed at helping employers prioritize health and safety as they develop plans and polices for their employees to return to the workplace (NSC, May 17, 2021). Through SAFER, the NSC and HAA developed a web-based decision tool to guide employers on health, legal, and other considerations to prioritize the health and safety of workers. Due to the Delta Variant surge of new COVID–19 cases across the United States, the NSC and HAA revised the SAFER resources, including the online tool, to include information about employer requirements for COVID–19 vaccinations. These include guides for developing plans and policies to support employee vaccination through mandates and incentives; the collection and maintenance of COVID–19 vaccination records; and various considerations for testing unvaccinated workers. (HAA and NSC, September 17, 2021). The availability of these publicly-accessible tools to help employers develop vaccination policies further reduces any potential barriers for covered employers to establish and implement a written policy requiring each employee to be fully vaccinated against COVID–19, or alternatively to establish a policy allowing employees to choose whether to be fully vaccinated or tested for COVID–19 at least every seven days and wear face coverings.

The HAA maintains an online list of large companies requiring vaccinations for all or part of their workforce or customers. OSHA reviewed the list of companies, drawn from news reports and employer websites, with requirements for COVID–19 vaccination. Most of the companies listed require some or all employees to be vaccinated against COVID–19 while allowing medical exemptions or reasonable accommodations for disability or religious reasons. There are currently 188 listed companies across numerous industry sectors, including Amtrak, Deloitte, Google, The Walt Disney Company, Walmart, and the U.S. Chamber of Commerce.[21]

While healthcare employers subject to 29 CFR 1910.502 are not covered by this ETS, a number of large healthcare employers have implemented mandatory vaccine policies. This also shows the feasibility of the employers implementing mandatory vaccination requirements, often on large scales. According to the American Hospital Association (AHA), over 1,800 hospitals

[21] *https://www.healthaction.org/resources/vaccines/covid-19-vaccines-employer-requirements-health-action-alliance?0405d6f4_page=1* (last visited October 2, 2021).

have one or more vaccination requirements in place (Becker's Hospital Review, October 11, 2021). Large healthcare employers mandating that their employees be vaccinated include Kaiser Permanente, the nation's largest integrated, nonprofit health care organization with more than 216,000 employees and more than 23,000 physicians (Kaiser Permanente, August 2, 2021); Trinity Health, one of the largest multi-institutional Catholic health care delivery systems in the nation, with more than 123,000 employees and 90 hospitals in 22 states (Trinity Health, July 8, 2021); Sanford Health, which operates in 26 states and employs nearly 50,000 people (Sanford Health, July 22, 2021); and Genesis Health Care, a large U.S. nursing home chain with over 40,000 employees working in more than 250 centers across 23 states (Genesis Health Care, September 29, 2021).

Under paragraph (d)(2), if employers do not establish and implement a written mandatory vaccination policy, the employer must establish and implement a written policy allowing any employees not subject to a mandatory vaccination policy to either choose to be fully vaccinated or regularly tested for COVID–19 and wear a face covering. A substantial number of employers already have such policies in place. For example, the ASU WEF survey shows that 30% of employers surveyed require unvaccinated employees to participate in mandatory COVID–19 testing and 30% of employers require face coverings for unvaccinated employees (ASU WEF, September 2021).

OSHA also notes a number of state COVID–19 vaccination requirements. In response to the Delta Variant surge, 19 states have implemented written COVID–19 vaccination and testing policies for state employees and 23 states have done so for healthcare employees (NASHP, October 1, 2021). For example, on September 20, 2021, the Colorado Department of Public Health and Environment (CDPHE) implemented policies requiring state employees and personnel at health care facilities and hospitals to be fully vaccinated against COVID–19. All state employees must either be fully vaccinated against COVID–19 or participate in twice-weekly testing. Employees are allowed work time to get tested and administrative or Public Health Emergency Leave to get vaccinated. Employees who are not fully vaccinated must wear masks inside state facilities when they are around others. On August 30, 2021, the State Board of Health approved a vaccine requirement for personnel in health care settings with high-risk patients. All personnel affected by this rule needed to receive their first dose of COVID–19 vaccine by September 30, 2021, and must be fully vaccinated by October 31, 2021 (CDPHE, September 17, 2021).

A number of local governments have also implemented policies requiring COVID–19 vaccination or testing for employees. For example, the Fulton County Board of Commissioners in Georgia recently approved a ''Vax or Test'' policy requiring employees to get vaccinated or tested for COVID–19 each week. Since September 6, 2021, Fulton County has required all County employees, as a condition of employment, to either be vaccinated against COVID–19 or be tested weekly for COVID–19 unless an employee is granted a reasonable accommodation (Fulton County Government, September 03, 2021). The multitude of local, state, and employer vaccination or testing mandates across the country support OSHA's finding that such policies are feasible.

II. Determining Employee Vaccination Status

Paragraph (e) of the ETS requires employers to determine the vaccination status of each employee. Employers must require employees to provide an acceptable proof of vaccination status, including whether they are fully or partially vaccinated. As discussed in *Summary and Explanation* (Section VI. of this preamble), acceptable proof of vaccination status is: (i) The record of immunization from a health care provider or pharmacy; (ii) a copy of the COVID–19 Vaccination Record Card; (iii) a copy of medical records documenting the vaccination; (iv) a copy of immunization records from a public health, state, or tribal immunization information system; or a copy of any other official documentation that contains the type of vaccine administered, date(s) of administration, and the name of the health care professional(s) or clinic site(s) administering the vaccine(s). A signed and dated employee attestation is acceptable in instances when an employee is unable to produce proof of vaccination. Given the attestation option, there are no technological barriers to the provision for proof of vaccination status. As discussed below, many employers requiring proof of vaccination have successfully implemented such policies even without allowing the flexibility of the attestation option.

The employer must maintain a record and a roster of each employee's vaccination status. This information is subject to applicable legal requirements for confidentiality of medical information. These records must be preserved while the ETS is in effect. OSHA is not aware of any technological challenges that the large employers covered by this ETS would face with respect to collecting and maintaining records. This is a performance-based requirement, meaning that employers have the flexibility to structure their systems to fit within current systems, such as those relating to personnel records, tax records, and other sensitive or confidential records gathered and maintained by large employers.

A number of the surveys discussed above also show that most employers with vaccine mandates require proof of vaccination. For example, ASU WEF workplace COVID–19 survey from fall 2021 found that 60% of employers that required vaccinations also required proof of vaccination from employees. The NSC study from June 2021 found that 45% of employers with COVID–19 vaccination requirements required proof of vaccination, such as submitting a copy of the COVID–19 vaccination card. An additional 30% of employers surveyed verify employee vaccination status through self-reporting based on the honor system.

Additionally, a large-scale survey conducted by the Willis Towers Watson consulting firm between August 18 and 25, 2021, showed that a majority of employers currently track their employees' vaccination status. Nearly one thousand employers responded to this survey, and they collectively employ 9.7 million workers from industries across the public and private sectors including manufacturing, general services, wholesale and retail, IT and telecom, healthcare, financial services, energy and utilities, and public sector and education (Willis Towers Watson, June 23, 2021). Nearly six in 10 (59%) currently track their workers' vaccination status and another 19% are planning or considering doing so later this year. A majority (62%) of those employers who currently track their workers' vaccination status require proof of vaccination, such as CDC vaccination cards, while 36% rely on employees to self-report (Willis Towers Watson, September 1, 2021).

Other evidence in the record also supports the feasibility both of gathering proof of vaccination and determining employees' vaccination status. Many large employers with vaccination policies require employees to submit proof of vaccination. For example, Tyson Foods requires employees to submit proof of vaccination to Tyson

Foods Vaccination Verification Program in order to qualify for the company's vaccination incentive (Tyson Foods, August 3, 2021). Similarly, Capital One bank requires all employees, contractors, vendors, and visitors to Capital One facilities to show proof of vaccination. (Capital One, August 11, 2021). The International Union of Painters and Allied Trades (IUPAT), which represents 140,000 craftspeople in the U.S. and Canada and has implemented vaccine requirements for its members, also requires all of its own non–bargaining unit office and field employees to show proof of vaccination. (IUPAT, May 10, 2021).

CVS Health, a health conglomerate with more than 300,000 employees, including more than 40,000 physicians, pharmacists, nurses and nurse practitioners, has mandated COVID–19 vaccination for its nurses, pharmacists and other employees who interact with patients and requires proof of vaccination for those employees (CVS Health, August 23, 2021).

The surveys and employer policies reviewed by OSHA all support the agency's finding that it is feasible for employers to determine their employees' vaccination status and collect proof of vaccination.

III. Providing Support for Vaccination

Paragraph (f) of the ETS requires employers to support COVID–19 vaccination for each employee by providing a reasonable amount of time to each employee for vaccination and reasonable time and paid sick leave to each employee for side effects experienced following vaccination. The feasibility of paying for the time is addressed in OSHA's economic analysis.

This technological feasibility determination focuses on whether employers would encounter obstacles in implementing payment policies that would make this requirement infeasible for the large employers covered by this ETS. OSHA has determined that there are no such obstacles. Most significantly, OSHA has already required this type of system for employers covered by the Healthcare ETS and nearly four months after that ETS took effect, OSHA is not aware that employers covered by that ETS experienced any technological compliance difficulties with respect to that requirement. In addition, many employers have already implemented policies such as those required to comply with this new ETS as a way of incentivizing employee vaccination. For example, the ASU WEF workplace COVID–19 survey from fall 2021 found that 60% of employers surveyed offered incentives for employees to be vaccinated. These incentives ranged from additional paid time off, cash, the ability to bypass regular testing and/or daily health screening requirements, and gifts. Eighteen percent of surveyed employers already provide additional time off for COVID–19 vaccination. Moreover, the NSC survey found that 86% of surveyed organizations had implemented policies such as paid time off, assistance with scheduling and transportation, and/or onsite vaccination.

OSHA's review of plans and best practice documents from the HAA registry and from other publicly-available sources also inform OSHA's finding that it is feasible for large employers to support employee vaccination (HAA, October 10, 2021). As part of this review, OSHA analyzed the ways that employers are currently supporting employee vaccination. One employer in the restaurant industry, the Fifty/50 Group, a Chicago-based restaurant group comprised of 14 establishments that requires employees to be fully vaccinated, offers paid time off for anyone getting a vaccine or feeling the mild after-effects. (Fifty/50 Group, May 18, 2021). Another employer in the animal slaughtering and processing industry, Tyson Foods, requires COVID–19 vaccinations for its U.S. workforce and also offers $200 and up to four hours of regular pay if employees are vaccinated outside of their normal shift or through an external source (Tyson Foods, August 3, 2021). In addition, Tyson Foods supports onsite vaccination events in collaboration with local health departments and healthcare providers to improve accessibility to vaccination. Tyson Foods has hosted more than 100 vaccination events at its locations across the country.

The evidence in the record demonstrates that many employers are already offering the types of vaccination support required by paragraph (f). Combined with OSHA's previous finding for a similar provision in the Healthcare ETS and the lack of compliance difficulties reported while that ETS has been in effect, OSHA therefore finds this requirement is technologically feasible.

IV. COVID–19 Testing for Employees Who Are Not Fully Vaccinated

Paragraph (g) of the ETS requires employers to ensure that employees who are not fully vaccinated and who report at least once every seven days to a workplace where other individuals such as coworkers or customers are present are: (1) Tested for COVID–19 at least once every seven days; and (2) provide documentation of the most recent COVID–19 test result to the employer no later than the seventh day following the date the employee last provided a test result. Employers must also ensure that employees who are not fully vaccinated and do not report during a period of seven or more days to a workplace where other individuals are present are: (1) Tested for COVID–19 within seven days prior to returning to the workplace; and (2) provide documentation of that test result upon return to the workplace.

Employees who are not fully vaccinated must be tested with a COVID–19 test, which is a test for SARS–CoV–2 that is: (i) Cleared, approved, or authorized, including in an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) to detect current infection with the SARS–CoV–2 virus (*e.g.,* a viral test); (ii) administered in accordance with the authorized instructions; and (iii) not both self-administered and self-read unless observed by the employer or an authorized telehealth proctor. Examples of tests that satisfy this requirement include tests with specimens that are processed by a laboratory (including home or on-site collected specimens which are processed either individually or as pooled specimens), proctored over-the-counter tests, point of care tests, and tests where specimen collection is either done or observed by an employer.

COVID–19 testing has become more widely available throughout the pandemic and as of September 2021, the FDA has authorized approximately 250 tests and collection kits that diagnose current infection with the SARS–CoV–2 virus and may be acceptable under the ETS (FDA, September 10, 2021), and by October 1, 2021, the number of EUAs issued had grown to 324 (FDA, October 1, 2021). The ETS permits compliance through use of a wide range of FDA-authorized tests that are readily available, so there is little doubt that testing itself is technologically feasible.

This technological feasibility analysis therefore focuses on whether testing will continue to be readily available in quantities sufficient to meet the potential increase in testing demand while this ETS is in place. Given the wide variety of tests that can be used to comply with this ETS and OSHA's review of information about the existing manufacturing and distribution capabilities of test manufacturers, the agency does not anticipate feasibility issues related to ensuring that

employees can get access to one of the acceptable tests within the time frames required by the ETS.

a. Brief Overview of Testing and Administration

COVID–19 tests that are cleared, approved, or authorized, including in an Emergency Use Authorization (EUA), by the FDA to detect current infection with the SARS–CoV–2 virus (*e.g.,* a viral test) satisfy the ETS. FDA-cleared, approved, or authorized molecular diagnostic tests and antigen tests are permitted under the ETS when used as authorized by the FDA and with a Clinical Laboratory Improvement Amendments of 1988 (CLIA) certification when appropriate. As described in the *Summary and Explanation* for paragraph (g) (Section VI.G. of this preamble), NAATs are a type of molecular test that detect genetic material. As of October 14, 2021, the FDA had issued EUAs for 264 molecular COVID–19 tests including tests specified to be used ''with certain conditions of authorization required of the manufacturer and authorized laboratories'', 81 of which are authorized for home collection. Additionally, the FDA has issued EUAs for 2 OTC molecular COVID–19 test kits available without a prescription (FDA, October 14, 2021b).

NAATs, such as real-time reverse transcription-polymerase chain reaction (RT–PCR), have greater accuracy than antigen tests. However, most FDA-authorized NAATs need to be processed in a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (referred to as a ''CLIA-certified laboratory'') with variable time to results (~1–2 days). While the NAAT test is a more reliable test, the antigen test is faster and less expensive.

An antigen test is an in vitro diagnostic test used to detect active SARS–CoV–2 infection. As of October 14, 2021, the FDA had issued 37 EUAs for COVID–19 antigen tests, including eight EUAs for over-the-counter (OTC) antigen tests that can be used without a prescription (FDA, October 14, 2021a).

Administration of an antigen test that meets the definition of COVID–19 test under this ETS falls into one of several categories: OTC employee self-tests that are observed by employers or authorized telehealth proctors; point-of-care (POC) or OTC tests performed by employers with a CLIA certificate of waiver; and other FDA cleared, approved, or authorized antigen tests that are analyzed in a CLIA certified laboratory setting (FDA, October 14, 2021a). The FDA has authorized POC tests that can be used at a place of employment when the facility is operating under a CLIA certificate of waiver. A CLIA certificate of waiver can be issued by CMS and may, when consistent with FDA's authorization, allow a laboratory to run a SARS–CoV–2 test outside a high or moderate complexity traditional clinical laboratory setting (CDC, September 9, 2021). In accordance with the CLIA certificate of waiver, the laboratory or POC testing site must use a test authorized for that location, like an FDA EUA POC test, and must adhere to the authorized test instructions to avoid human error. Certain COVID–19 antigen diagnostic tests can be analyzed on-site (where the person took the nasal swab) when that facility is operating under a CLIA certificate of waiver, while others must be analyzed in a CLIA certified high or moderate complexity laboratory setting. Some COVID–19 antigen diagnostic tests are authorized for use at home, without the need to send a sample to a laboratory. Antigen tests generally return results in approximately 15–30 minutes. The CDC provides training materials created by test manufacturers for POC antigen testing and reading of results for SARS–CoV–2 (CDC, July 8, 2021).

COVID–19 antigen diagnostic tests are found at physician offices; urgent care facilities; pharmacies, such as CVS or Walgreens; school health clinics; long-term care facilities and nursing homes; temporary locations, such as drive-through sites managed by local organizations; and other locations across the country (CDC, July 8, 2021; CVS Health, October 2021; Walgreens, October 8, 2021). The availability of government-offered antigen tests varies by state, and may be free or subsidized and accessible without a prescription or physician note (RiteAid, October 2021; Walgreens, October 2021; HHS, June 11, 2021). The Department of Health and Human Services (HHS) provides a publicly-available list of community-based testing locations in each state that offer free COVID–19 testing for insured and uninsured residents (HHS, August 17, 2021). Pharmacies and other locations often provide antigen tests by appointment, although some will allow testing for walk-ins (CVS Health, September 2021; Walgreens, October 8, 2021). COVID test kits are currently available from several on-line retailers (Amazon, October 12, 2021).

b. Testing Frequency

The ASU WEF survey data also supports OSHA's finding that the requirement for employees who are not fully vaccinated to be tested at least every seven days is feasible. The ASU WEF found that 73% of survey surveyed employers (797 employers) had testing policies for their workforce, and 76% of those employers had implemented mandatory testing requirements. Additionally, 25% of employers with testing polices had implemented requirements for routine testing of a portion of or the entire workforce, and 41% no longer require testing for fully vaccinated employees. Of the employers that test employees, 27% of those perform viral testing daily and 46% perform viral test once a week. Finally, 38% of companies exclusively administer polymerase chain reaction (PCR) tests (PCR tests are a type of NAAT), 17% exclusively administer antigen tests, and 45% administer both. Companies administer a range of COVID–19 tests and conduct testing at a variety of locations (some companies use more than one location). Forty-two percent of companies test workers at health testing laboratories, 35% test onsite at work, 28% test at hospitals, 23% test at retail pharmacies, 13% test at universities, 9% test at home to be sent a lab for evaluation, and 5% test at home for immediate results (ASU WEF, September 2021).

OSHA also evaluated evidence of employers' current testing efforts by reviewing existing COVID–19 practices developed by employers, trade associations, and other organizations. Based on its review, OSHA concludes that it is feasible for most covered employees (and therefore their employers) to be tested in compliance with the ETS requirements for frequency of testing.

OSHA notes that there are several options for large employers to consider if they want to help facilitate testing for employees who are not vaccinated. Delta Airlines, for example, currently requires weekly COVID–19 testing for all of its employees who are not vaccinated, and the company has engaged the Mayo Clinic Laboratories to help design the employee testing program, assist in administering diagnostic and serology tests, and analyze the results to determine broader trends and provide recommendations to Delta's existing policies and procedures (Mayo Clinic Laboratories, June 30, 2020). Delta Airlines also operates onsite testing in cities with large employee populations including Atlanta, Minneapolis, and New York. It recently extended an at-home specimen collection option to all U.S. employees, through which Quest Diagnostics will send self-collection kits directly to an employee's doorstep upon request and support complete laboratory confirmation for results (Delta, August 25, 2021).

c. Availability of COVID–19 Tests

In the spring and early summer months of 2021, demand for tests decreased as vaccinations began to increase and the number of COVID–19 cases declined before the Delta surge and some manufacturers slowed production of COVID–19 tests. However, the number of tests performed daily has grown considerably over the summer due to the Delta Variant surge and re-openings of workplaces and schools. In parallel with the Delta surge, COVID–19 testing has increased from a daily average of about 450,000 in early July 2021 to about 1.8 million by mid-September 2021, or roughly 12.6 million per week (JHU, October 8, 2021). This data does not include any self-administered OTC tests, which will be discussed below.

OSHA's review of the evidence shows that the increasing rate of production of COVID–19 tests is more than adequate to meet rising demand related to compliance with the ETS testing option before the 60-day delayed testing compliance date (see paragraph (m)(2)(ii)). This determination is largely based on the number of tests with FDA EUAs actively being produced through the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx) initiative described below.

According to the Johns Hopkins University of Medicine Coronavirus Resource Center, the total tests administered in August 2021 was approximately 44.4 million (or approximately 11.1 million per week). Id. During that same month, the total tests produced by the NIH RADx contracts was approximately 121 million (which would average to 30.25 million per week), resulting in a substantial surplus of available tests (NIBIB, September 28, 2021). As discussed in *Economic Analysis*, Section IV.B. of this preamble, Table IV.B.8, OSHA estimates that as many as 7.2 million tests may be administered weekly under this standard; however, 7.2 million is almost certainly an overestimate because it does not exclude employees who are already required to be tested by their employers and would continue to be tested at the same frequency after the ETS. Even if testing is increased by 7.2 million tests per week because of the ETS, that would still mean a surplus of nearly 12 million tests per week beyond what would be need to continue at current testing levels with the addition of ETS-related tests (30.25 − 11.1 − 7.2 = 11.95 million surplus per week).

The total number of tests administered during June, July, and August 2021, the period of the summer including the Delta Variant surge and other reasons for substantial testing increases such as re-opening of schools, was approximately 87 million tests, an average of approximately 6.7 million per week (JHU, October 8, 2021). During that period, more than 400 million COVID–19 tests were produced through the NIH RADx initiative, or roughly 33 million per week. OSHA anticipates that this surplus of tests will continue to increase the availability of tests that can be used to comply with the ETS.

The data from the Johns Hopkins Coronavirus Resource Center is collected from state and county government sources, so it does not include any self-administered OTC tests. Additionally, while all states report PCR testing, not all states report antigen testing. Nevertheless, the data from Johns Hopkins Coronavirus Resource Center is the best available evidence from which to estimate the total number of tests administered during a given period of time. Even though the number of administered tests reported through the Johns Hopkins Coronavirus Resource Center does not include unreported OTC tests, the NIH RADx program data shows a large surplus and sufficient additional COVID–19 test capacity relative to the number of administered tests reported. Additionally, the NIH RADx program will further allow for increased test distribution through retail markets and will address any increase in demand due to companies that may stockpile tests. This increased availability will strengthen test capacity, further enabling compliance with the ETS testing provision (NIBIB, September 28, 2021). OSHA has determined that even with an estimated additional 7.2 million tests administered weekly due to the ETS (see *Economic Analysis* (Section IV.B. of this preamble)), there are sufficient COVID–19 tests available to allow for both employers and employees to obtain COVID–19 tests through a variety of retail sources (*e.g.,* local pharmacies, on-line purchasing as discussed above).

Determinations of testing capacity are aggregate measures of domestic and global market and supply chains. Throughout the pandemic, diagnostic testing capacity has been stressed by the increased demand, as some products that are part of a global market cannot adapt by simply increasing manufacturing in one country (*e.g.,* laboratory instruments), and other products manufactured domestically require capital investments to address rising demands (*e.g.,* extraction kits) (CRS, February 25, 2021). As discussed below, because of the substantial investments made, OSHA projects that the diagnostic testing capacity can meet the increased demand due to this ETS.

OSHA evaluated multiple projections of current and future testing capacity and determined that projections related to the NIH initiatives discussed below are the most reliable estimates of current and future testing capacity for its technological feasibility assessment. Test manufacturers receiving NIH, FDA, and Biomedical Advanced Research and Development Authority (BARDA) (a component of HHS) funding as part of these programs undergo a submission and authorization process where their production capacity and pipeline are assessed and production quantities are validated. As explained below, as of August 2021, the NIH data indicates testing capacity stands at about 30 million tests per week, and capacity continues to grow (NIBIB, September 28, 2021). OSHA notes that this number underestimates the total number of tests available each week, as it only includes companies that have received funding for tests and testing supplies through the NIH initiatives described below.

The NIH has identified constraints on testing capacity as an area of focus and investment since the beginning of the COVID–19 pandemic, and OSHA examined potential constraints on testing capacity as part of its feasibility analysis. As described below, massive investments in testing capabilities, particularly in underserved areas, have largely mitigated issues with the availability of COVID–19 tests. Further, testing capacity continues to grow as new tests are developed and brought to market and manufacturers can ramp up supply to meet any future testing demands if need be.

The FDA has authorized more than 320 tests and collection kits that diagnose current infection with the SARS–CoV–2 virus and may be acceptable under the ETS (FDA, October 1, 2021). Among other criteria, the standard allows for the use of tests with specimens that are processed by a CLIA certified laboratory (including home or on-site collected specimens which are processed either individually or as pooled specimens), proctored over-the-counter tests, point of care tests, and tests where specimen collection and processing is either done or observed by an employer. As explained above, many employers across various industry sectors have already implemented policies for onsite testing. The use of FDA-authorized POC tests by these employers would be compliant with the testing provision of the ETS if the entity administering the test holds a CLIA

certificate as required by the EUA. COVID–19 OTC tests that are both self-administered and self-read by employees do not satisfy the testing requirement unless observed by the employer or an authorized telehealth proctor. In the event that the employer is merely observing the employee conduct a test, a CLIA certificate would not be needed.

There have been extensive investments, including by the federal government, to help ensure that COVID–19 tests are widely available. Section 2401 of the American Rescue Plan appropriated $47,800,000 to the Secretary of the HHS, to remain available until expended, to carry out activities to detect, diagnose, trace, and monitor SARS–CoV–2 and COVID–19 infections and related strategies to mitigate the spread of COVID–19. Funds were made available to implement a national testing strategy; provide technical assistance, guidance, support, and awards grants or cooperative agreements to State, local, and territorial public health departments; and support the development, manufacturing, procurement, distribution, and administration of tests to detect or diagnose SARS–CoV–2 and COVID–19; and establish federal, state, local and territorial testing capabilities.

On April 29, 2020, the NIH established the RADx initiative with a $1.5 billion investment. The RADx initiative has used this funding to speed development of rapid and widely-accessible COVID–19 testing (NIH, April 29, 2020). On October 6, 2020, the NIH and BARDA established the RADx Technology (RADx-Tech) and RADx Advanced Technology Platforms (RADx-ATP) programs to speed innovation in the development, commercialization, and implementation of technologies for COVID–19 testing specifically for late-stage scale-up projects. Through the RADx Tech and RADx-ATP programs, the NIH and BARDA have awarded a total of $476.4 million in manufacturing expansion contracts supporting a combined portfolio of 22 companies in the U.S. (NIH, October 6, 2020).

These programs have significantly increased testing capacity throughout the country. Since being established, RADx has worked closely with the FDA, the CDC, and BARDA to move more advanced diagnostic technologies swiftly through the development pipeline toward commercialization and broad availability. On April 28, 2021, the Institute of Electrical and Electronic Engineers (IEEE) dedicated a special issue in the Journal of Engineering in Medicine and Biology exploring the innovative structure and operation of the RADx Tech program and determined that the initiatives had succeeded in dramatically increasing COVID–19 testing capacity in the United States. The IEEE report found that the RADx Tech/ATP programs, in conjunction with BARDA and the FDA, had streamlined and bolstered the national COVID–19 testing capacity. At the time of the report, the RADx Tech/ATP programs had increased the number of testing makers to 150 companies that, as a result of the NIH/BARDA investments, had the capacity to produce up to 1.9 million tests per day (IEEE, April 28, 2021).

The NIH RADx-TECH/ATP initiative entered its second phase on September 28, 2021, and at that time the supported companies had collectively produced over 500 million tests, received 27 FDA authorizations, and developed the first OTC COVID–19 test for use at home. These September 2021 investments are supporting late stage development of innovative point-of-care and home-based tests, as well as improved clinical laboratory tests that will increase the capacity of testing in the U.S. A full list of active contracts and supported U.S. COVID–19 testing manufacturers can be found on the NIH RADx-TECH/ATP programs: Phase 2 awards (NIBIB, October 14, 2021).

The following example shows the NIH RADx EUA pipeline process. On May 9, 2020, the FDA authorized the first EUA for a COVID–19 antigen test, a new category of tests for use in the ongoing pandemic. Quidel was awarded a contract under the NIH RADx TECH/ATP phase 1 initiative for the Sofia 2 SARS Antigen FIA for use in high and moderate complexity laboratories certified by CLIA, as well as for point-of-care testing by facilities operating under a CLIA certificate of waiver (FDA, May 9, 2020). On July 31, 2020, Quidel announced that it had received a contract for $71 million under the NIH RADx TECH/ATP program, phase 1, to accelerate the expansion of its manufacturing capacity for production of the SARS–CoV–2 rapid antigen test and quickly exceeded that capacity (Quidel Corp., July 31, 2020). On March 31, 2021, the FDA then authorized a second EUA from Quidel under contract with the NIH RADx initiative for the QuickVue At-Home OTC COVID–19 Test, another antigen test where certain individuals can rapidly collect and test their sample at home, without needing to send a sample to a CLIA certifed laboratory for analysis (FDA, March 31, 2021). Furthermore, based on the success of the Quidel for the Sofia 2 SARS Antigen FIA increasing production capacity, the NIH granted another $70 million contract for manufacturing Capacity Scale-Up for Sofia SARS Antigen and Sofia Influenza A+B/SARS FIAs on June 11, 2021 (FDA, June 11, 2021).

The RADx-TECH/ATP initiative maintains a dashboard of manufacturer testing data from supported U.S. firms. OSHA reviewed the data available on the dashboard as part of its determination of feasibility. In August 2021, the data showed that U.S. manufacturers supported by the NIH RADx-TECH/ATP were producing approximately 30 million tests per week (NIBIB, September 28, 2021).

While consumers in some parts of the country have encountered difficulty obtaining rapid at-home tests, on October 4, 2021, the FDA granted EUA for the ACON Laboratories Flowflex COVID–19 Home Test, which is anticipated to double rapid at-home testing capacity in the United States within weeks (and well before compliance dates for testing required by this ETS) (FDA, October 4, 2021). By the end of the 2021 (ahead of the paragraph (g) compliance date), the manufacturer plans to produce more than 100 million tests per month and plans to produce more than 200 million tests per month by February 2022 (FDA, October 4, 2021). On October 6, 2021, the Administration announced a plan to buy $1 billion worth of rapid at-home COVID–19 tests; this purchase, coupled with the October 4 authorization of the Flowflex COVID–19 test, is expected to increase the number of available at-home COVID–19 tests to 200 million per month by December 2021 (Washington Post, October 6, 2021).

These investments have had a pronounced impact on the availability of testing and employers' use of testing in the workplace. ASU's recent report, *How Work has Changed: The Lasting Impact of COVID–19 on the Workplace*, ascribed the jump in the percentage of employers that test their employees from 17% in the fall of 2020 to 70% in the fall of 2021 in large part to the increased availability of testing. In particular, the report noted that by the spring of 2021, ''it became relatively easy to acquire tests and hire testing service providers. There are more labs and companies with EUA's and most have enough capacity that there are few shortages.'' (ASU WEF, September 2021).

Moreover, to ensure a broad, sustained capacity for COVID–19 test production, multiple COVID–19 test manufacturers have been mobilized by authority of the Defense Production Act. Under the Administration's plan to increase COVID–19 testing, the federal

government will directly purchase and distribute 280 million- rapid point-of-care and over-the-counter at-home COVID–19 tests, sending 25 million free at-home rapid tests to community health centers and food banks. These actions will provide tests for use by communities to build adequate stockpiles, as well as the sustained production to be able to scale up production as needed in the future. Additionally, to ensure convenient access to free testing, 10,000 pharmacies will be added to the Department of Health and Human Services free testing program.

In response to rising demands for testing, U.S. manufacturers have increased production of COVID–19 test kit, reagents, and supplies. Advanced Medical Technology Association (AdvaMed), a trade group for testing manufacturers, reported that its members are ramping up production of rapid point-of-care test supplies to meet demand and that laboratory-based testing capacity for test confirmation is strong. AdvaMed has created a national COVID–19 Diagnostic Supply Registry of COVID–19 test manufacturers that support state and federal governments in their pandemic responses. Registry participants are thirteen leading diagnostic manufacturers whose tests together comprise approximately 75–80% of the COVID–19 in vitro diagnostic devices (IVD) on the market in the U.S. While these manufacturers produce a majority of molecular COVID–19 tests, they do not produce a majority of the total COVID–19 tests manufactured. These COVID–19 test manufacturers collectively shipped approximately 3.8 million tests in July 2021, 8.2 million tests in August 2021, and 9.4 million molecular tests for the week ending September 4th, 2021 (AdvaMed, September 10, 2021). While these figures are not representative of the total weekly testing capacity in the U.S., this data demonstrates that testing capacity has grown significantly over the past few months and reflects the success manufacturers have had in ramping up production of tests.

While current test availability is sufficient to meet the increased testing demands due to the ETS, OSHA is also confident that the RADx-TECH/ATP initiatives will continue to spur testing capacity and growth. The RADx-TECH/ATP initiatives have focused on moving test makers' products through the late stage pipeline and securing FDA authorization for entry into the market. So far, there have been 27 such authorizations. As of September 2021, there were 824 eligible late-stage scale up proposals from various test makers up for review for NIH/BARDA funding. Furthermore, 517 of these submissions are for the authorization and production of multiple types of COVID–19 tests including one or more of the following: Blood, sputum, nasal swab, oral swab, fecal, saliva, or other types. OSHA considers this to be further support for its determination that testing capacity will continue to grow and that increased COVID–19 testing supplies are on the horizon (NIBIB, September 28, 2021).

Based on data from the Johns Hopkins Coronavirus Resource Center, which examined publicly-available data from multiple sources, approximately 12.4 million tests were conducted during the week of August 26–September 2, 2021. As noted earlier, in the economic analysis of this ETS, OSHA projects testing rates to increase by approximately 7.2 million tests per week starting 60 days after publication of the ETS. As described above, many employers are currently testing their workforce. This 7.2 million is almost certainly an overestimate because it does not exclude employees who are already required to be tested by their employers and would continue to be tested at the same frequency after the ETS. The data reviewed by OSHA on the RADx-TECH/ATP Dashboard shows that the manufacturers supported by the initiative are producing approximately 30 million tests per week, and capacity continues to grow. As explained above, it is expected that roughly 50 million at-home COVID–19 tests will be available each week by December 2021. OSHA therefore finds that there are (and will continue to be) sufficient COVID–19 tests available to meet the anticipated demand related to compliance with paragraph (g) by the 60-day delayed compliance date.

d. Availability of COVID–19 Test Supplies

OSHA has also analyzed the availability of COVID–19 test supplies for use by COVID–19 test kit manufacturers, diagnostic laboratories, and determined that there are sufficient supplies to allow compliance with the ETS testing option. The COVID–19 pandemic and recent Delta Variant surge have caused some disruptions in the availability of testing supplies such as swabs, viral transport medium, RNA extraction kits, serology consumables, diagnostic reagents, plastic consumables, and diagnostic instruments. The COVID–19 testing supply market is driven by the need to rapidly screen large segments of the population and deliver test results. The data presented throughout this assessment has shown demand for laboratory COVID–19 tests is rising across the country.

Testing for COVID–19 involves many different components that are manufactured, transported, and used independently (*e.g.,* bulk solvents, extracting reagents, packaging) or semi-independently (*e.g.,* test kits). Most of the supplies used in COVID–19 testing are disposable, requiring a constant sustained capacity for new supplies. Some distribution channels move supplies directly to medical and laboratory end-users and others move supplies through distributors. In either case, the combination of increased testing demand and the established supply chains indicate that testing kits will be available in sufficient quantities throughout the country, including in rural areas where large employers may be located.

There have been substantial investments from federal and state programs and private industry to stimulate the production and distribution of testing supplies to bolster testing capacity across the country. Many products, such as swabs and reagents for RNA extraction kits, exhibited rising demand and, at some point during the pandemic, were subject to shortages that threatened continued testing capacity. For example, there was only one domestic manufacturer of medical grade flocked swabs, Puritan Medical Products Company of Guilford, Maine, and the company's pre-pandemic capacity was insufficient to meet demand of increased testing in the early period of the COVID–19 pandemic (Puritan Products, April 20, 2020). On July 29, 2020, the Department of Defense (DOD), in coordination with the Department of Health and Human Services, awarded $51.15 million to Puritan to expand industrial production capacity of flock tip testing swabs (DOD, July 31, 2020). On March 26, 2021, Puritan was awarded another $146.77 million to increase the company's total production capacity to 250 million foam tip swabs per month at its Tennessee facility by February 2022 (DOD, March 29, 2021).

Other private sector companies were mobilized to change the products they manufactured to accelerate production of COVID–19 test components, such as swabs, reagents, and solvents for RNA extraction kits. For example, Microbrush, a U.S.-based manufacturer of sterile applicators for the dental industry, began production of a nasopharyngeal test swab to meet the growing demand for COVID–19 testing requirements in July 2020. The Microbrush test swabs are sterilized and individually packaged in a medical-

grade pouch intended for nasopharyngeal sample collection such as in dental procedures and also COVID–19 testing (Microbrush, July 1, 2020).

RNA extraction kits are used by the majority of NAAT protocols. These kits are sets of consumable plastic laboratory materials (small centrifuge tubes, filters, and collection vials) and chemical reagents (solutions for breaking the virus apart and purification) assembled by a manufacturer. Each kit has enough materials to process several dozen samples. The use of RNA extraction kits is not exclusive to COVID–19 testing, meaning that a market existed pre-COVID–19, and manufacturers were able to adapt to fluctuations in demand spurred by the pandemic.

There are multiple companies with facilities in the United States that produce RNA extraction kits for the domestic market that have been awarded federal grants to increase the supply of COVID–19 test kits and reagent supplies. For example, in December 2020, the DOD and HHS identified several key reagents with the potential for supply chain bottlenecks and awarded a $4.8 million Indefinite Delivery/Indefinite Quantity contract to Anatrace Products, LLC to support increased production of key reagents for sample processing; Polyadenylic Acid (Poly A), Guanidinium Thiocyanate (GTC), and Proteinase K (Pro K) to process samples (DOD, December 21, 2020). Additionally, QIAGEN (based in Germany with U.S. manufacturing in Germantown, Maryland) produces extraction kits for authorized COVID–19 tests and has responded to the pandemic by scaling their production to around the clock production to strengthen testing kit capacity (Qiagen, October 2, 2021). On August 23, 2021, DOD, on behalf of and in coordination with HHS, awarded a $600,000 contract to QIAGEN to expand manufacturing capacity of enzymatic reagents and reagent kits used in COVID–19 molecular diagnostic tests, thereby allowing QIAGEN to increase its monthly production of reagent kits by 7,000 and enzymes by 5,100 milligrams by the end of February 2022 to support domestic laboratory testing for COVID–19 (DOD, August 23, 2021).

Additionally, manufacturers of raw materials and solvents for COVID–19 test kits have implemented strategies to strengthen their portions of the COVID–19 test supply chain. Millipore Sigma, a large producer of solvents and raw materials for tests, has created a global task force to actively evaluate the overall supply chain of products and key raw material suppliers to mitigate any potential disruption of COVID–19 testing capacity (Millipore Sigma, October 2021). In light of the foregoing, OSHA believes that there is sufficient—and increasing—availability of COVID–19 testing supplies to enable compliance with the ETS testing option.

e. Sufficiency of Laboratory Capacity

As noted above, a wide range of tests are acceptable under the ETS, including those that can be observed by employers without laboratory processing. Moreover, there has been rapid growth in the availability of OTC tests that do not require laboratory processing. Authorized OTC tests self-administered by employees and proctored by the employer do not require a CLIA certificate of waiver.

The Association of Public Health Laboratories (APHL) has conducted weekly surveys of its membership to monitor their current and projected capability and capacity to test for COVID–19. Data from this survey is used to inform HHS, FEMA, CDC, and other federal partners to support public health laboratory supply and reagent needs. OSHA reviewed the weekly COVID–19 survey results through the APHL COVID–19 Lab Testing Capacity and Capability Data Dashboard. The data comes from voluntary participation in the weekly surveys collected from approximately 100 state, local and territorial public health laboratories (PHLs) and reported to the CDC. The APHL weekly survey data supports OSHA's feasibility determination and demonstrates that COVID–19 testing demand will be met. For example, from August 15, 2021 to September 12, 2021, the APHL weekly survey data found that 96–100% of PHLs are meeting their current testing demand since the Delta Variant surge began (APHL, September 27, 2021).

Laboratory capacity for processing and confirmation of at-home COVID–19 rapid tests provided by manufacturer retailers such as Walmart has also increased. Laboratory and diagnostic service providers have implemented parallel strategies to strengthen laboratory capacity for confirmation of at-home COVID–19 rapid tests available on the market for employers and employees to utilize. For example, Quest Diagnostics, which is the laboratory processing the samples and delivering results to those tested at Walmart's drive-through and curbside testing sites, has scaled up laboratory testing capacity and rapid antigen test inventory should demand increase (Walmart, July 9, 2021). Quest Diagnostics has added COVID–19 testing platforms in laboratories in regions where demand is comparatively high and has implemented an online consumer-initiated test service for individuals and small businesses to request COVID–19 testing. In August 2021, Quest Diagnostics began to offer clinician-guided rapid COVID–19 antigen testing to employers through a guided telehealth visit using a self-administered, nasal swab antigen test that provides results in 15 minutes that is then shipped to a Quest Diagnostics lab for confirmation (Quest Diagnostics, September 28, 2021).

Based on the evidence reviewed, OSHA has determined that there is adequate laboratory capacity to enable compliance with the ETS testing option.

f. Access to Testing in Underserved Communities

Individuals in underserved communities (including Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality) are disproportionately burdened by the COVID–19 pandemic as many individuals in these communities are essential workers who cannot work from home, increasing their risk of being exposed to the virus. Access to COVID–19 testing in these communities has been identified as contributing factor to COVID–19 related health disparities in these communities. For example, the NSC June 2021 survey found that the most common barrier to testing for rural employers and workers is access to vaccination and testing sites (NSC, September 2021).

Several federal efforts have recently been implemented to strengthen testing capabilities in underserved communities. The NIH has invested heavily to improve COVID–19 testing in underserved communities throughout the COVID–19 pandemic. On September 30, 2020, the NIH received nearly $234 million to improve COVID–19 testing for underserved and vulnerable populations that have been disproportionately affected by this pandemic and launched the RADx Underserved Populations (RADx-UP) program (NIH, September 30, 2020).

The RADx-UP program has primary components supported by these NIH grants to increase availability, accessibility, and acceptance of testing among underserved and vulnerable populations. The RADx-UP program also provides overarching support and

guidance on administrative operations and logistics, facilitating effective use of COVID–19 testing technologies, supporting community and health system engagement, and providing overall infrastructure for data collection, integration, and sharing from a coordination and data collection center (NIH, September 30, 2021). Through the RADx-UP program, the NIH has continued to support the needs of underserved populations and is currently funding 70 community-based projects across the country (NIH, September 30, 2021).

The CDC has also focused its efforts to improve COVID–19 testing in underserved communities throughout the COVID–19 pandemic. For example, on September 20, 2021, Maine Health, the largest health care organization in Maine and also serving northern New Hampshire, was awarded nearly $1 million for COVID–19 testing in higher risk communities (Maine Health, September 20, 2021). In March 2021, the CDC implemented a plan to invest $2.25 billion over two years to address COVID–19 related health disparities and advance health equity among populations that are at high-risk and underserved, including racial and ethnic minority groups and people living in rural areas. Since that time, the CDC has awarded grants to public health departments to improve testing capabilities; improve data collection and reporting; and build, leverage, and expand infrastructure support for testing (CDC, March 17, 2021). On September 30, 2021, the CDC awarded an $8.1 million grant to the Arizona Center for Rural Health (ACRH) to address COVID–19 disparities across Arizona by improving the delivery of COVID–19 testing to rural and underserved communities (ASU CRH, September 30, 2021). A number of other federal and state government agencies have been expanding support for COVID–19 testing in underserved communities as well. On June 11, 2021, HHS through the Health Resources and Services Administration (HRSA) provided $424.7 million in American Rescue Plan funding to over 4,200 Rural Health Clinics (RHCs) for COVID–19 testing (HHS, June 11, 2021).

Private industry has also mobilized considerably to increase access and testing capacity in rural and other underserved communities. The NSC June 2021 survey found that a common barrier to employers and employees in rural and other underserved communities is transportation and access to vaccination and testing sites (NSC, September 2021). In its final report, the NSC recommended employers in these communities host on-site vaccinations to increase worker access. Applications for mobile vaccination are available on most local and state health department websites (NSC, September 2021; ASU WEF, September 2021).

CVS has collaborated with several organizations, including the National Medical Association, to increase access to testing in underserved communities and has developed mobile solutions that allow health care professionals to bring testing capabilities to businesses in these communities as they re-open (CVS Health, September 2021). Walgreens has implemented efforts to increase access in underserved communities such as rural and/or lower socioeconomic communities as well, with now more than half of Walgreens testing sites currently located in areas the CDC has identified as socially vulnerable and underserved (Walgreens, October 2021). Because of these investments, OSHA concludes that employers and their employees in underserved communities, including those in rural areas, will have sufficient access to COVID–19 tests and will be able to comply with the ETS's testing requirements for employees who are not fully vaccinated.

V. Management of Confidential Medical Records, Including Employee COVID–19 Vaccination and Testing Records

The ETS requires employers to maintain a record of each employee's vaccination status. Employers must also maintain a record of each test result provided by each employee. These records must be maintained as confidential medical records and must not be disclosed except as required or authorized by this ETS or other federal law. The records are not subject to the retention requirements of 29 CFR 1910.1020(d)(1)(i) but must be maintained and preserved while the ETS is in effect.

Other OSHA rules have a similar requirement to maintain employee medical records, which could include vaccination records. See, *e.g.*, Bloodborne Pathogens (29 CFR 1910.1030), Respiratory Protection (29 CFR 1910.134), Respirable Crystalline Silica (29 CFR 1910.1053), Beryllium (29 CFR 1910.1024), Lead (29 CFR 1910.1025), and OSHA's requirements for employee access to medical and exposure records (29 CFR 1910.1020). OSHA is not aware of any potential technological feasibility issues related to recordkeeping.

The requirement under this ETS to maintain records of employees' COVID–19 vaccination status and COVID–19 test results is similar to requirements in the aforementioned OSHA standards, and OSHA therefore concludes that compliance is feasible. Employers subject to the ETS will be able to comply with the provisions in the ETS using straightforward recordkeeping systems that are already widely used by large employers as part of their usual and customary business practices. OSHA concludes that it is feasible for such employers to comply with the requirements in the ETS for maintaining records related to COVID–19 vaccination status and COVID–19 test results.

VI. Other Provisions

There are no technological feasibility barriers related to compliance with other requirements in the ETS (*e.g.,* face coverings, employee notification). As explained above, many of the employer plans and best practice documents reviewed by OSHA indicate that employers have implemented the measures in these provisions across industry sectors. OSHA highlights two of the ETS's other requirements below, which are explored in more depth in other sections of this preamble.

- Face Coverings. Paragraph (i) of the ETS requires the employer to ensure that all employees who are not fully vaccinated wear a face covering when indoors and when occupying a vehicle with another person for work purposes, except: (i) When an employee is alone in a room with floor to ceiling walls and a closed door; (ii) for a limited time while the employee is eating or drinking at the workplace or for identification purposes in compliance with safety and security requirements; (iii) when employees are wearing respirators or face masks; or (iv) where the employer can show that the use of face coverings is infeasible or creates a greater hazard. The definition of face covering allows various different types of masks, including clear face coverings or cloth face coverings with a clear plastic panel which may be used to facilitate communication with people who are deaf or hard-of-hearing or others who need to see a speaker's mouth or facial expressions to understand speech or sign language respectively. The types of face coverings permitted under this ETS are widely used and readily available. The results of the ASU WEF June 2021 survey found that 30% of employers required face coverings for unvaccinated employees, which demonstrates that this provision of the ETS is currently being implemented by a substantial number of employers and is ''capable of being done.'' (ASU WEF, September 2021). OSHA identifies no technological

feasibility issues with this provision of the ETS.

• Notification. Paragraph (h) of the ETS contains COVID–19 notification requirements for both the employer and the employee. Under this provision, the employer must require each employee to promptly notify the employer if they receive a positive COVID–19 test or are diagnosed with COVID–19 by a licensed healthcare provider and must immediately remove any employee from the workplace who receives a positive COVID–19 test or is diagnosed with COVID–19 by a licensed healthcare provider. OSHA identifies no technological feasibility issues in connection with the ETS's notification requirements. It is the employer's responsibility to ensure that appropriate instructions and procedures are in place so that designated representatives of the employer (e.g., managers, supervisors) and employees conform to the rule's requirements.

VII. Conclusion

OSHA has determined that complying with this ETS is technologically feasible for typical firms covered by this standard, at least most of the time (see *Public Citizen* v. *OSHA*, 557 F.3d 165 (3d Cir. 2009); *Lead I*, 647 F.2d at 1272; *Lead II*, 939 F.2d at 990). OSHA reviewed extensive evidence across industries and did not identify any industry-specific compliance barriers. Evidence in the record that shows that the written workplace COVID–19 vaccination policy requiring each employee to be fully vaccinated against COVID–19 unless they establish and implement a written policy that permits an employee to choose to be tested for COVID–19 at least every seven days and wear a face covering is feasible. In fact, such policies have already been implemented by hundreds of large companies across industry sectors. OSHA has also determined that there are sufficient COVID–19 tests available and adequate laboratory capacity to meet the anticipated increased testing demand related to compliance with the ETS testing option.

Additionally, the ETS's requirements to determine employee vaccination status, support employee vaccination by providing time off for vaccination and time off for recovery, and maintain records of employee COVID–19 vaccination status and COVID–19 test results are also technologically feasible. As discussed above, that many employers and organizations have already implemented such requirements demonstrates that they are ''capable of being done.'' Moreover, the recordkeeping requirements in this ETS largely mirror the requirements for the collection and maintenance of similar employee medical records in OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) and the Respiratory Protection standard (29 CFR 1910.134). The ETS provides a flexible compliance option for employers to tailor their procedures and practices to the needs of their workplace. OSHA finds that employers in typical firms in all industry sectors can comply with the requirements of the ETS, and compliance with the ETS is therefore technologically feasible.

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B. Economic Analysis

I. Introduction

This section presents OSHA's estimates of the costs and impacts, anticipated to result from the COVID–19 Vaccination and Testing ETS, 29 CFR 1910.501. The purpose of this ETS is to address the grave danger of COVID–19 in the workplace by promoting vaccination, while allowing an alternative for face covering and testing requirements, and also to remove COVID–19 positive workers from the workplace regardless of vaccination status. The estimated costs are based on employers achieving full compliance with the requirements of the ETS. They do not include prior costs associated with firms whose current practices are already in compliance with the ETS requirements. The purpose of this analysis is to:

- Identify the entities/establishments and industries affected by the ETS;
- Estimate and evaluate the costs and economic impacts that regulated entities/establishments will incur to achieve compliance with the ETS; and
- Evaluate the economic feasibility of the rule for affected industries.

In this analysis, OSHA is fulfilling the requirement under the OSH Act to show the economic feasibility of this ETS. This analysis is different from the cost portion of a regulatory impact analysis prepared in accordance with Executive Order 12866 in that the agency is focused only on costs to employers when evaluating economic feasibility. In a regulatory impact analysis, the costs to all parties (*e.g.*, employers, employees, and governments) are included. While this is not the case for an economic feasibility analysis, it does not necessarily mean that the ETS imposes no costs or burdens on parties other than employers. For example, the rule imposes certain costs on employees who choose not to become vaccinated (*e.g.*, for face coverings and testing. While these costs are not relevant for the purpose of establishing economic feasibility, these costs would be attributable to the ETS in a regulatory impact analysis. In addition, these costs are not mandatory because any employee who does not wish to pay them may choose to become vaccinated or leave employment (see discussion below on turnover), after which the costs would not be incurred. Some employees may also be entitled to a reasonable accommodation that may avoid additional cost (*e.g.*, telework).

''[T]he Supreme Court has conclusively ruled that economic feasibility [under the OSH Act] does not involve a cost-benefit analysis.'' *Pub. Citizen Health Research Grp.* v. *U.S. Dept. of Labor*, 557 F.3d 165, 177 (3d Cir. 2009); see also *Asbestos Info. Ass'n*, 727 F.2d at 424 n.18 (noting that formal cost benefit is not required for an ETS, and indeed may be impossible in an emergency). The OSH Act ''place[s] the 'benefit' of worker health above all other considerations save those making attainment of this 'benefit' unachievable.'' *Cotton Dust*, 452 U.S. at 509. Therefore, ''[a]ny standard based on a balancing of costs and benefits by the Secretary that strikes a different balance than that struck by Congress would be inconsistent with the command set forth in'' the statute. Id. While this case law arose with respect to health standards issued under section 6(b)(5) of the Act, which specifically require feasibility, OSHA finds the same concerns applicable to emergency temporary standards issued under section 6(c) of the Act. An ETS ''serve[s] as a proposed rule'' for a section 6(b)(5) standard, and therefore the same limits on any requirement for cost-benefit analysis should apply. Indeed, OSHA has also rejected the use of formal cost benefit analysis for safety standards, which are not governed by section 6(b)(5). See 58 FR 16,612, 16,622–23 (Mar. 30, 1993) (''in OSHA's judgment, its statutory mandate to achieve safe and healthful workplaces for the nation's employees limits the role monetization of benefits and analysis of extra-

workplace effects can play in setting safety standards.'').[22] A standard must be economically feasible in order to be ''reasonably necessary and appropriate'' under section 3(8) and, by inference, ''necessary'' under section 6(c)(1)(B) of the OSH Act. Cf. *Am. Textile Mfrs. Inst., Inc.* v. *Donovan*, 452 U.S. 490, 513 n.31 (1981) (noting ''any standard that was not economically . . . feasible would a fortiori not be 'reasonably necessary or appropriate' '' as required by the OSH Act's definition of ''occupational safety and health standard'' in section 3(8)); see also *Florida Peach Growers*, 489 F.2d at 130 (recognizing that the promulgation of any standard, including an ETS, must account for its economic effect). A standard is economically feasible when industries can absorb or pass on the costs of compliance without threatening industry's long-term profitability or competitive structure, *Cotton Dust*, 452 U.S. at 530 n.55, or ''threaten[ing] massive dislocation to, or imperil[ing] the existence of, the industry.'' *United Steelworkers of Am.* v. *Marshall*, 647 F.2d 1189, 1272 (D.C. Cir. 1981) (*Lead I*). Given that section 6(c) is aimed at enabling OSHA to protect workers in emergency situations, the agency is not required to make the showing with the same rigor as in ordinary section 6(b) rulemaking. *Asbestos Info. Ass'n/N. Am.* v. *OSHA*, 727 F.2d 415, 424 n.18 (5th Cir. 1984). In *Asbestos Information Association*, the Fifth Circuit concluded that the costs of compliance were not unreasonable to address a grave danger where the costs of the ETS did not exceed 7.2% of revenues in any affected industry. Id. at 424.

The scope of judicial review of OSHA's determinations regarding feasibility (both technological and economic) ''is narrowly circumscribed.'' *N. Am.'s Bldg. Trades Unions* v. *OSHA*, 878 F.3d 271, 296 (D.C. Cir. 2017) (*Silica*). ''OSHA is not required to prove economic feasibility with certainty, but is required to use the best available evidence and to support its conclusions with substantial evidence.'' *Amer. Iron & Steel Inst.* v. *OSHA*, 939 F.2d 975, 980–81 (D.C. Cir. 1991) (*Lead II*); 29 U.S.C. 655(b)(5), (f). ''Courts, [moreover], 'cannot expect hard and precise estimates of costs.' '' *Silica*, 878 F.3d at 296 (quoting *Lead II*, 939 F.2d at 1006). Rather, OSHA's estimates must represent ''a reasonable assessment of the likely range of costs of its standard, and the likely effects of those costs on the industry.'' *Lead I*, 647 F.2d at 1266. The ''mere 'possibility of drawing two inconsistent conclusions from the evidence,' or deriving two divergent cost models from the data 'does not prevent [the] agency's finding from being supported by substantial evidence.' '' *Silica*, 878 F.3d at 296 (quoting *Cotton Dust*, 452 U.S. at 523).

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of the intended regulation and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Because of the continued impact of the pandemic on occupational safety and health, OSHA has prepared this ETS and the accompanying economic analysis on an extremely condensed timeline. Thus, in light of the Secretary's conclusion that the COVID–19 pandemic constitutes an emergency situation, the Secretary has notified OIRA that it is necessary for OSHA to promulgate this regulation more quickly than normal review procedures allow, pursuant to E.O. 12866 Sec. 6 (a)(3)(D). OIRA has waived compliance with Sec. 6(a)(3)(B) and (C) for this economically significant rule.

II. COVID–19 ETS Industry Profile

a. Introduction

In this section, OSHA provides estimates of the number of affected entities, establishments, and employees for the industries that have settings covered by this ETS. The term ''entity'' describes a legal for-profit business, a non-profit organization, or a local governmental unit, whereas the term ''establishment'' describes a particular physical site of economic activity. Some entities own and operate more than one establishment.

Throughout this analysis, where estimates were derived from available data those sources have been noted in the text. Estimates without sources noted in the text are based on agency expertise.

b. Scope of the COVID–19 ETS

This ETS applies to all employers with a total of 100 or more employees at any time this ETS is in effect. However, the requirements of this ETS do not apply to: (1) Workplaces covered under the Safer Federal Workforce Task Force COVID–19 Workplace Safety: Guidance for Federal Contractors and Subcontractors (Contractor Guidance); or (2) settings where any employee provides healthcare services or healthcare support services when subject to the requirements of 29 CFR 1910.502 (*i.e.*, the Healthcare ETS). Furthermore, the requirements of this ETS do not apply to the employees of covered employers: (1) Who do not report to a workplace where other individuals, such as coworkers or customers, are present; or (2) while working from home; or (3) who work exclusively outdoors. Based on this scope, employers in nearly every sector are expected to be covered by this ETS.

OSHA's assumptions may result in an overestimate of the number of employees affected by the ETS. First, OSHA is not estimating the number and type of workplaces covered by the Safer Federal Workforce Task Force COVID–19 Workplace Safety: Guidance for Federal Contractors and Subcontractors or removing them from the profile of employers affected by this ETS. OSHA assumes for the purpose of this analysis that employers covered under the Contractor Guidance will also have contracts to perform work in workplaces where they are not covered under that Guidance (*i.e.*, where the employer contracts with an entity other than the federal government), and so those employers are included in the scope here.

Second, OSHA estimates that all employers in all private sector industries are affected by this ETS to some extent. Although this ETS imposes no compliance burden on employers whose employees work remotely 100 percent of the time, in OSHA's analysis, no employers with 100 or more employees have all of their employees working remotely 100 percent of the time (*i.e.*, at least some employees in each affected firm do not work remotely). Moreover, OSHA's analysis does not take into account that some employees may engage in part-time telework (*i.e.*, it assumes that employees either work remotely full-time or do not work remotely at all). Finally, OSHA's analysis does not fully take into account the exemption for employees who do not report to a workplace where other individuals are present, meaning that this analysis may overestimate the number of employees affected by the rule.

As stated, the requirements of this ETS do not apply to the employees of covered employers who work

[22] To support its Asbestos ETS, OSHA conducted an economic feasibility analysis on these terms. 48 FR 51086, 51136–38 (Nov. 4, 1983). In upholding that analysis, the Fifth Circuit said that OSHA was required to show that the balance of costs to benefits was not unreasonable. *Asbestos Info. Ass'n*, 727 F.2d at 423. As explained above, OSHA does not believe that is a correct statement of the economic feasibility test. However, even under that approach this ETS easily passes muster.

exclusively outdoors. To determine the percentage of employees in occupations for which the exception is relevant, the agency uses data from the BLS's 2020 Occupational Requirements Survey (ORS) (BLS, 2020). This survey looks at various aspects of job requirements. In particular, the survey lists occupations where workers are outdoors ''constantly,'' which OSHA interprets as being nearly continuously outdoors. Because the majority of workers who work outdoors ''constantly'' likely work indoors at least some of the time, the agency judges that no more than 10 percent of the workers who are primarily outdoors are actually there exclusively. See Table IV.B.1 for the occupations, the ORS percentages, and final percentages for workers OSHA estimates are exempt from the scope of this ETS based on the outdoor work exemption.

Table IV.B.1-Occupations with workers who work outdoors

SOC Code	Occupation	Percent outdoors constantly	Percent outdoors exclusively
373011	Landscaping and Groundskeeping Workers	90%	9%
472061	Construction Laborers	79%	8%
474051	Highway Maintenance Workers	48%	5%
339092	Lifeguards, Ski Patrol, and Other Recreational Protective Service	45%	5%
470000	Construction and Extraction Occupations	42%	4%
471011	First-Line Supervisors of Construction Trades and Extraction	39%	4%
472073	Operating Engineers and Other Construction Equipment Operators	36%	4%
370000	Building and Grounds Cleaning and Maintenance Occupations	26%	3%
272022	Coaches and Scouts	14%	1%
530000	Transportation and Material Moving Occupations	8%	1%
390000	Personal Care and Service Occupations	5%	0.5%
270000	Arts, Design, Entertainment, Sports, and Media Occupations	2%	0.2%

Source: BLS Occupational Requirement Survey (BLS, 2020), OSHA calculations.

OSHA's estimate of employees who work exclusively outdoors does not account for employers who only need to make slight adjustments to their current work practices to ensure that their employees qualify for the outdoor exemption, such as by holding tool box talks outdoors instead of in a traditional indoor location. This may result in more employees falling within the exemption than estimated by OSHA; therefore, OSHA's cost analysis likely overestimates costs.

The requirements of the ETS also do not apply to settings where any employee provides healthcare services or healthcare support services when subject to the requirements of 29 CFR 1910.502 (the Healthcare ETS). The Healthcare ETS is a temporary standard that may not remain in effect for the entire period that 29 CFR 1910.501 remains in effect. This means that some employers or employees covered by the Healthcare ETS, those in firms that have 100 or more employees, may ultimately be covered by 29 CFR 1910.501 (because the exception in 29 CFR 1910.501 is limited to when employers are subject to the requirements of the Healthcare ETS). This potentially impacts two types of costs: Employer-based costs (*e.g.*, employer policy on vaccination) and employee-based (periodic) costs (*e.g.*, recordkeeping).

Employer-Based Costs: For the purpose of the economic analysis only, OSHA treats the Healthcare ETS as though it will no longer be in effect after December, 2021, because at that point the Healthcare ETS will have been in effect for the six months that OSHA had calculated costs for that ETS. Therefore, OSHA estimates that some employers including those with 100 or more employees subject to the 29 CFR 1910.502 exemption, will need to take employer-based costs because all these employers will ultimately be subject to 29 CFR 1910.501 under this assumption.

Employee-Based Costs: OSHA's estimates incorporate two assumptions for the purposes of this analysis only. First, for the purposes of assumptions for this analysis only, § 1910.501 will remain in effect for 6 months. Second, many employers and employees currently covered only by the Healthcare ETS will be subject to the requirements of 29 CFR 1910.501 for approximately 4 months (4 months of the 6 month estimated lifespan of 29 CFR 1910.501). OSHA's estimate of those employees exempted by the Healthcare ETS was based on the Industry Profile of employees in firms with 100 employees or more covered by the Healthcare ETS, as estimated in Table VI.B.3 in the economic analysis for that rulemaking (see 86 FR 32488).

OSHA notes that some employees currently covered by the Healthcare ETS might also be currently covered by 29 CFR 1910.501 (albeit at different times or in different locations) because the Healthcare ETS is settings-based. For example, a pharmacist would normally not need to comply with the requirements of § 1910.502 when just filling prescriptions in a retail pharmacy store (see 29 CFR 1910.502(a)(2)(ii)), but would need to comply when administering vaccinations within an embedded clinic inside that retail pharmacy. Thus, there are a number of variables that could impact the extent to which the pharmacist's employer might

incur any costs. However, even to the extent that such costs might occur (*e.g.*, recordkeeping for testing if the pharmacist works for an employer covered by 29 CFR 1910.501 and is unvaccinated), OSHA judges that they would be *de minimis* for several reasons. First, this pool of workers is likely to be very small, especially when compared to the population of workers covered by the Healthcare ETS. Second, most employees subject to both standards will have been fully vaccinated before OSHA takes costs for these employees under 29 CFR 1910.501 by operation of the CMS rule mandating vaccination or as a result of the voluntary vaccination incentives promoted by OSHA's Healthcare ETS (therefore negating most of the costs associated with vaccination and testing under 29 CFR 1910.501). Third, any underestimate of periodic costs will only apply during the first two months after 29 CFR 1910.501 goes into effect and the standard has a delayed compliance date of 30 days after the effective date for most provisions, except for testing, which has a delayed compliance date of 60 days. This will further lessen the periodic costs associated with any potential underestimate.

In all respects (other than the 4/6 share of employee-based costs), OSHA is taking the same approach in the Industry Profile and Cost Estimates for employers and employees currently covered by the Healthcare ETS as it does for all other industries. These employers and employees are fully integrated into Table IV.B.5, below, which contains a summary of covered entities and employees. Moreover, the same assumptions on outdoor work and other scope exemptions that OSHA explains earlier holds for these employers and employees. In addition, OSHA makes the same downward adjustment in telework for these employers and employees in accordance with the methodology it sets out below. Thus, the Healthcare ETS profile used in this ETS to account for employees exempted by the Healthcare ETS into the Profile in the event the Healthcare ETS expires (i.e., in Table IV.B.5, below) is an updated version of Table VI.B.3 in the Healthcare ETS (see 86 FR 32488).[23] OSHA notes that some firms may decide to proactively comply with certain 29 CFR 1910.501 requirements (such as mandating vaccination for all employees that were removed from the Industry Profile) before the end date of the Healthcare ETS based on the conclusion that 29 CFR 1910.501 will ultimately apply in full to them. Since these costs still occur due to 29 CFR 1910.501, OSHA is appropriately including them in this cost analysis.

There are 9.9 million employees who will newly be covered by 29 CFR 1910.501 starting in December whose employers will incur an additional $318 million in costs. These costs are integrated into the agency's main cost analysis, which is described later in this economic analysis.

Only some state- and local-government entities are included in this analysis. State- and local-government entities are specifically excluded from coverage under the OSH Act (29 U.S.C. 652(5)). Workers employed by these entities only have OSH Act protections if they work in states that have an OSHA-approved State Plan. (29 U.S.C. 667). Consequently, this analysis excludes public entities in states that do not have OSHA-approved State Plans. Table IV.B.2 presents the states that have OSHA-approved State Plans and their public entities are included in the analysis.

Table IV.B.2. States that Have OSHA-Approved State Plans

Alaska	Maryland	South Carolina
Arizona	Michigan	Tennessee
California	Minnesota	Utah
Connecticut	Nevada	Vermont
Hawaii	New Jersey	Virginia
Illinois	New Mexico	Washington
Indiana	New York	Wyoming
Iowa	North Carolina	US Virgin Islands
Kentucky	Oregon	
Maine	Puerto Rico	

Source: OSHA, September 25, 2021

OSHA notes, finally, that the percentage of employers mandating vaccination, and hence the employee vaccination rate, would likely rise to some degree absent this ETS due to other federal actions, such as the vaccination mandate for federal contractors, the CMS rule published elsewhere in this issue of the **Federal Register**, and as a result of vaccination mandates that have been adopted at state and local levels. This analysis does not account for increases in vaccination that would occur absent the standard, resulting in a likely overestimate of the costs.

c. Teleworking

Dingel-Neiman Approach for Estimating Who Can Work Remotely

OSHA uses the estimates in a paper by J.I. Dingel and B. Neiman, ''How Many Jobs Can be Done at Home?,'' published in July 2020, as a starting point to determine the percentage of employees, by occupation, who are not expected to work remotely (*i.e.*, the percentage of workers for whom employers have employee-based costs under this ETS) (Dingel and Neiman, July 2020).

In Dingel and Neiman's paper, the authors estimate the number of jobs in the U.S. economy that workers can feasibly perform remotely. The authors use two different surveys from the

[23] The CMS rule published elsewhere in this issue of the **Federal Register** mandates vaccination for employees in facilities that receive Medicare or Medicaid. OSHA is ignoring this for the purpose of its cost analysis and taking costs into account as if the CMS rule were not promulgated. This creates a substantial overestimate.

Occupational Information Network (O*Net) [24] to evaluate which occupations can be performed remotely and combine the O*Net estimates with the Bureau of Labor Statistics' (BLS) Occupational Employment and Wage Statistics (OEWS) data on employment by occupation to estimate the total number of workers nationally who can work remotely.

To evaluate the survey responses, Dingel and Neiman first determined the occupations for which the average response to a given prompt met a preset threshold. Table IV.B.3 presents the Dingel and Neiman response threshold for each survey question as well as the percent of occupations that meet each respective predetermined threshold. For example, in 10.8 percent of occupations, the average response to the ''Performing general physical activities'' (4.A.3.a.1) question met the threshold, falling in the range of 4 to 5.

Dingel and Neiman determined that employees in a given occupation can telework full time if they did not meet the predetermined threshold for any of the questions highlighted in grey and denoted with a ''Yes'' in the column that reports whether that activity is used in determining whether a job can be done remotely in Table IV.B.3.

[24] 24 The O*Net Program is a major source of occupational information for the U.S. The O*NET database surveys ask both specific occupational experts and workers in those occupations questions covering multiple aspects of almost 1,000 occupations covering the entire U.S. economy. See *https://www.onetonline.org/* for more information. The occupation definitions in the O*NET data are Standard Occupation Codes—the same definitions that are used in the BLS OEWS data. Dingel and Neiman use the responses to two surveys included in release 24.2 of the database administered by O*NET, the Worker Context Questionnaire and the Generalized Work Activities Questionnaire. The occupation with the median number of respondents had 26 respondents for each work context question and 25 respondents for each generalized work activities question per detailed-level SOC occupation code.

In the O*Net Questionnaires, survey respondents responded to statements about the nature and requirements of the daily tasks associated with their job on a 1–5 ordinal scale, where 5 represents the strongest agreement and 1 represents the strongest disagreement (see Table IV.B.3). The O*Net data contain the average response to each question for each occupation code. For instance, for occupation ''Chief Executives'' (SOC 11–1011), the average response to the prompt ''Performing General Physical Activities is very important'' was 1.39, indicating that performing general physical activity is not, on average, critical to the work of chief executives. The average responses by occupation for other prompts in the relevant surveys utilized by Dingel and Neiman are contained in those surveys.

Table IV.B.3. O*Net Survey Questions and Response Thresholds

Question ID	Question description	Response threshold	Perc. of occupations that meet threshold	Used to estimate ability to work remotely
Generalized Work Activities Survey				
4.A.3.a.1	Performing General Physical Activities is very important	4 to 5	10.8%	Yes
4.A.3.a.2	Handling and Moving Objects is very important	4 to 5	12.7%	Yes
4.A.3.a.3	Controlling Machines and Processes [not computers nor vehicles] is very important	4 to 5	13.1%	Yes
4.A.3.a.4	Operating Vehicles, Mechanized Devices, or Equipment is very important	4 to 5	9.2%	Yes
4.A.4.a.8	Performing for or Working Directly with the Public is very important	4 to 5	16.2%	Yes
4.A.3.b.4	Repairing and Maintaining Mechanical Equipment is very important	4 to 5	4.0%	Yes
4.A.3.b.5	Repairing and Maintaining Electronic Equipment is very important	4 to 5	2.1%	Yes
4.A.1.b.2	Inspecting Equipment, Structures, or Materials is very important	4 to 5	18.6%	Yes
Worker Context Survey				
4.C.2.d.1.a	Average respondent says they are sitting almost continually	4.5 to 5	12.2%	No
4.C.2.d.1.b	Average respondent says they are standing almost continually	4.5 to 5	10.1%	No
4.C.2.d.1.g	Majority of time is spent using your hands to handle, control, or feel objects, tools, or controls	3.5 to 5	46.2%	No
4.C.2.a.1.c	Majority of respondents say outdoors every day	4.5 to 5	8.3%	Yes
4.C.1.a.2.h	Average respondent says they use email less than once per month	1 to 2	15.4%	Yes
4.C.1.a.2.f	Average respondent says they use telephone less than once per month	1 to 2	4.1%	No
4.C.2.d.1.c	Average respondent says they spent majority of time climbing ladders, scaffolds, or poles	3.5 to 5	1.2%	No
4.C.2.d.1.d	Average respondent says they spent majority of time walking or running	3.5 to 5	13.4%	Yes
4.C.2.d.1.e	Average respondent says they spent majority of time kneeling, crouching, stooping, or crawling	3.5 to 5	2.4%	No
4.C.2.d.1.f	Average respondent says they spent majority of time keeping or regaining their balance	3.5 to 5	0.3%	No
4.C.2.d.1.h	Average respondent says they spent majority of time bending or twisting their body	3.5 to 5	12.1%	No
4.C.2.d.1.i	Average respondent says they spent majority of time making repetitive motions	3.5 to 5	31.1%	No
4.C.2.e.1.d	Average respondent says they spent majority of time wearing common or specialized protective or safety equipment	3.5 to 5	43.1%	Yes
4.C.1.a.4	Average respondent says they spent majority of time in contact with others	3.5 to 5	94.3%	No
4.C.1.b.1.f	Average respondent says it is very important for them to deal with external customers	4 to 5	28.7%	No
4.C.1.b.1.g	Average respondent says it is very important for them to coordinate or lead others	4 to 5	21.2%	No
4.C.1.c.1	Average respondent says it is very important for them to be responsible for others' health and safety	4 to 5	21.4%	No
4.C.1.d.3	Average respondent says they deal with violent people at least once a week	4 to 5	0.4%	Yes
4.C.2.a.1.b	Average respondent says they work in an environment that is not environmentally controlled every day	4.5 to 5	1.5%	No
4.C.2.a.3	Average respondent says they are physically close (at least moderately close) to others	4 to 5	20.9%	No
4.C.2.b.1.b	Average respondent says extreme temperatures every day	4 to 5	9.1%	No
4.C.2.b.1.d	Average respondent says they are exposed to contaminants at least once a week	4 to 5	20.0%	No
4.C.2.b.1.e	Average respondent says they are exposed to cramped work space every day	4.5 to 5	0.1%	No
4.C.2.b.1.f	Average respondent says they are exposed to whole body vibration at least once a week	4 to 5	1.0%	No
4.C.2.c.1.a	Average respondent says they are exposed to radiation at least once a week	4 to 5	1.1%	No
4.C.2.c.1.b	Average respondent says they are exposed to diseases or infection at least once a week	4 to 5	9.0%	Yes
4.C.2.c.1.c	Average respondent says they are exposed to high places at least once a week	4 to 5	2.2%	No
4.C.2.c.1.d	Average respondent says they are exposed to hazardous conditions at least once a week	4 to 5	6.0%	No
4.C.2.c.1.e	Average respondent says they are exposed to hazardous equipment at least once a week	4 to 5	9.9%	No
4.C.2.c.1.f	Average respondent says they are exposed to minor burns, cuts, bites, or stings at least once a week	4 to 5	2.6%	Yes

Source: (Dingel and Neiman, July 2020).

Adjusting Dingel and Neiman To Reflect Current Conditions

While many employees can and are working remotely, many have returned to their places of employment. This conclusion is borne out by BLS's Current Population Survey (CPS) (BLS, 2021c). To address the tendency toward employees returning to work on site and more accurately reflect current remote work conditions, OSHA made two adjustments to Dingel and Neiman's estimates. In the COVID–19 Healthcare ETS, OSHA also used Dingel and Neiman's paper to estimate the number of workers who teleworked in response to the pandemic and the ETS under the assumption that anyone who could work remotely would do so in response to the pandemic and the Healthcare ETS. Dingel and Neiman's estimates are therefore framed as the upper-bound of potential teleworking.

The adjustments OSHA made reflect changing circumstances. First, based on agency expertise, OSHA changed the status of certain occupations in its occupational list from working remotely to not working remotely. For example, when Dingel and Neiman published their study, many schools were operating virtually so the Dingel and Neiman finding that teachers were able to work remotely lined up with the situation where teachers were working remotely. At this point in the pandemic, on the other hand, in-person learning has mostly recommenced. To this end, OSHA changed the status of teachers and other employees in the education sector from working remotely to not working remotely in this analysis. As another example, many activities that ceased or were reduced significantly have now resumed and many locations that were closed to the public have reopened (*e.g.*, athletic events, shows, gyms, casinos and places of worship), and, since more people have returned to the office, there is more need for childcare. Therefore, OSHA also changed the status of these employees and others from telework to non-telework. This has the ultimate effect of increasing costs estimates for the rule.

Appendix A (Table A–1), in the accompanying document in the docket, ''Vaccination, and Testing ETS: Economic Profile and Cost Chapter Appendices'' (OSHA, October 2021b), presents Dingel and Neiman's (July 2020) unmodified percentages of workers that can work remotely in each detailed occupation (based on BLS's Standard Occupation Code (SOC)).[25] Appendix A also presents, in separate columns, percentages reflecting the modifications OSHA made in those occupations where OSHA changed the results from telework to non-telework for the reasons stated, as well as percentages reflecting the modifications made in occupations where employees work exclusively outdoors.

According to the OSHA-adjusted Dingel and Neiman estimates, 14 percent of the jobs in the United States are performed entirely at home, with significant variation across cities and industries. It should be noted that the Dingel and Neiman analysis does not specify a proportion of jobs that can be performed at home part of the time; under the analysis, employees are either working remotely full-time or are working on site full time.

The second adjustment OSHA made used monthly COVID-specific teleworking data from telework questions added during the pandemic to the CPS to estimate the reduction in teleworking since its peak and applied those estimates to further adjust downward the number of workers currently teleworking (BLS, 2021c). Specifically, the CPS questions asked respondents whether they were teleworking due to COVID–19 (as opposed to teleworking for other reasons) and OSHA estimated the difference in teleworking from the peak of COVID-related teleworking in all industries, which occurred in May 2020, through August 2021 (see Table IV.B.4).[26] The reduction in teleworking was then applied as the change in percentage points to the estimated overall level of employees covered by the ETS in each NAICS code estimated based on data from Dingel and Neiman (July 2020). OSHA's final teleworking estimates are provided in Appendix B in the accompanying document in the docket, ''Vaccination, and Testing ETS: Economic Profile and Cost Chapter Appendices'' (OSHA, October 2021b). Reductions due to employees working exclusively outdoors were applied to reduce the percentage of covered employees in Appendix B as well.

[25] Except for the adjustments to Dingel and Neiman discussed above, OSHA used the Dingel and Neiman estimates for telework by occupation without change. The agency recognizes that the authors' methodology (*i.e.*, the use of 0–1 thresholds) led to a small number of results that may appear not to reflect real-world experiences within an occupation. However, Dingel and Neiman represents the best available evidence for determining the percentage of employees, by occupation, who are expected to work remotely. OSHA is aware of no other source for this information that contains the level of detail necessary to conduct this analysis. Moreover, as explained above, OSHA modified the results for individual occupations when it had a reasoned basis for doing so. In any event, every NAICS industry is comprised of many occupations, so for every occupation where OSHA suspects remote work is overestimated in Dingel and Neiman's results, there may be another where remote work is underestimated.

[26] The CPS data were available only at the 2-digit NAICS level as shown in Table IV.B.4.

Table IV.B.4. Percent of Employees who Teleworked because of COVID-19

Industry	NAICS	May 2020	August 2021	Change
Agriculture and related industries	11	6.6%	3%	-4%
Nonagricultural industries		35.9%	14%	-22%
Mining, quarrying, and oil and gas extraction	21	33.2%	12%	-21%
Construction	23	14.7%	4%	-10%
Manufacturing		30.3%	13%	-17%
Durable goods manufacturing	31, 32	31.7%	14%	-18%
Nondurable goods manufacturing	33	28.2%	12%	-16%
Wholesale and retail trade		19.5%	6%	-13%
Wholesale trade	42	31.4%	10%	-21%
Retail trade	44, 45	16.7%	6%	-11%
Transportation and utilities		15.9%	7%	-9%
Transportation and warehousing	48, 49	11.8%	5%	-7%
Utilities	22	36.6%	20%	-17%
Information	51	61.0%	31%	-30%
Financial activities		60.1%	30%	-30%
Finance and insurance	52	66.8%	38%	-29%
Real estate and rental and leasing	53	41.9%	14%	-28%
Professional and business services		50.9%	26%	-25%
Professional and technical services	54	64.1%	36%	-29%
Management, administrative, and waste services	55, 56	23.7%	8%	-16%
Education and health services		45.6%	12%	-34%
Educational services	61	76.3%	14%	-62%
Health care and social assistance	62	25.4%	10%	-15%
Hospitals	622	21.2%	10%	-11%
Social assistance	624	37.8%	14%	-24%
Leisure and hospitality		15.0%	5%	-10%
Arts, entertainment, and recreation	71	37.9%	11%	-27%
Accommodation and food services	72	8.0%	3%	-5%
Other services	81	28.2%	8%	-20%
Private households	814	11.0%	2%	-9%
Public administration	92	45.5%	23%	-23%
Source: BLS Current Population Survey (BLS, 2021c)				

Other Teleworking Literature

A number of companies have announced plans to allow employees to work from home at least through the end of 2021—suggesting that the levels of remote work will not be returning to pre pandemic levels in the near future. Many technology and internet based companies, such as Dropbox, Coinbase, VMWare, and Slack, have announced a complete, permanent move to fully remote work (Courtney, September 27, 2021). Large employers such as Facebook, Amazon, and Siemens plan to maintain some physical workspace but now offer their employees who are telework eligible the option to work from home at least part of the time on a permanent basis (Id.). Google, Ford, Amazon, Apple and other large employers are expecting their telework eligible workers to return to on-site work (in some capacity) no earlier than January 2022 with Lyft anticipating a February 2022 return (Cerullo, August 31, 2021). As a final example, a survey of businesses in Massachusetts found that about 40 percent of teleworkers anticipate they will not be returning to the office in January 2022 or earlier (Chesto, June 22, 2021).

Additional studies provide qualitative support for the conclusion that a range of employees will ''predictably'' work from home both during the pandemic and beyond. In Bick, Blandin, and Martens's paper, ''Work from Home Before and After the COVID–19 Outbreak'' the authors use the following information to establish the physical location of employment (home or workplace) of workers: Data from the Real-Time Population Survey (RPS), a

national labor market survey of adults between ages 18–64 that mirrors the Current Population Survey (CPS) and collects information used in pandemic analysis, such as commuting behavior before and after the World Health Organization declared a global pandemic; mobility data on commuting; and information from the CPS since May 2020 on 'pandemic-related' telework (Bick et al., February 2021).

Based on these data, Bick et al., found that there was a sudden decline in commuting trips in the U.S. after the initial COVID–19 outbreak, and that even when these trips subsequently began increasing back toward the original number of commuting trips, the overall number of trips did not return to normal at the end of 2020 because many teleworking employees continued working from home. The authors found that the surge in work from home came almost entirely from employees working from home every workday in the reference week. The authors also suggest that, for some occupations, especially those occupations with more educated workers, the change to increased work from home appears to be a long-term change; the data showed that, as of December 2020, 12.5 percent of these workers reported they expect to be working from home full-time in the future, and 24.5 percent reported they expect to be working from home part-time.

In ''COVID–19 and Remote Work: An Early Look At U.S. Data,'' Brynjolfsson et al., noted that some of the shift to working from home seems to be a long-term phenomenon (Brynjolfsson et al., June 2020). The authors found, using an online survey, that 35.2 percent of workers had switched to working from home. Additionally, 15 percent of workers reported they were already working from home before COVID–19. Therefore, this study finds that about half of workers are now working from home—an even greater percentage than estimated by Dingel and Neiman.

Finally, in ''Why Working from Home Will Stick,'' Barrero et al. predict that 22 percent of all full workdays will be performed from home after the pandemic ends, compared to 5 percent before (Barrero et al., April 2021). The authors highlight five factors contributing towards the more permanent shift to telework: Diminished stigma, better-than-expected experiences working from home, investments in physical and human capital enabling work from home, reluctance to return to pre-pandemic activities, and innovation supporting work from home.

d. Affected Entities and Employees

OSHA used data from the U.S. Census' 2017 Statistics of U.S. Businesses (SUSB) to identify private sector entities and employees affected by this section of the ETS (U.S. Census Bureau, 2019), and used the BLS 2017 Quarterly Census of Employment and Wages (QCEW) to characterize state and local government entities (BLS, 2017). SUSB provides estimates of entities and employees by employer size range, which OSHA used to exclude employers with fewer than 100 employees.[27]

For rail transportation (NAICS 482), which is not included in SUSB or QCEW data, OSHA relied on Federal Railroad Administration and Association of American Railroads statistics reported in OSHA's 2020 final rule, *Cranes and Derricks in Construction: Railroad Roadway Work.* See 85 FR 57109 (September 15, 2020). OSHA used these data sources to identify public and private railroad employers with more than 100 employees. For agricultural NAICS (111 and 112), OSHA relies on the National Agricultural Statistics Service, 2017 Census of Agriculture (NASS, 2017) to obtain estimates of total entities, employees, and revenues. Since these data do not indicate the number of entities with more than 100 employees, OSHA assumes it is the same as the average proportion as the support activity sectors for crop and animal production (NAICS 114 and 115). OSHA similarly specifies teleworking conditions for NAICS 111 and 112 using the average result for support activities for agriculture (NAICS 114 and 115). For the postal service industry, NAICS 491110, which is not included in SUSB, OSHA obtains total entity and employment data for private postal services from the QCEW. Since these data do not indicate the number of entities with more than 100 employees, OSHA assumes it is the same as the average proportion as the related industries, couriers and express delivery (NAICS 492110), and local delivery (NAICS 492120).

OSHA used the BLS 2020 Occupational Employment and Wage Statistics (OEWS), which provides NAICS-specific estimates of employment and wages by occupation, along with the data in Appendix B (discussed earlier), to determine the subset of non-teleworking employees affected by the ETS.

Table IV.B.5 summarizes the set of entities covered by the ETS. OSHA estimates a total of approximately 263,879 entities and approximately 1.9 million establishments incur costs under the ETS.[28] OSHA estimates these entities employ approximately 102.7 million employees, and of these, OSHA estimates approximately 84.2 million employees are covered by the ETS and are not excluded from coverage by working remotely 100 percent of the time or exclusively outside.[29] For the purpose of this analysis, OSHA estimates that all employees that OSHA estimated will work remotely will continue to do so for the duration of this ETS.[30]

[27] SUSB with revenue data is only collected every 5 years. While OSHA could attempt to extrapolate these data to more recent years, the results would be imprecise because they would change the revenue-employee size distributions. Those distributions are crucial for measuring impacts so the agency has opted to use the data as is. The total number of employees in OSHA's estimate is fairly close to that of SUSB. The 2017 SUSB data includes a total of 128.6 million employees, while the more recent 2018 SUSB data includes a total of 130.9 million.

[28] This includes public entities only in states with an approved OSHA State Plan. See Table IV.B.2 above for further discussion of state plans.

[29] OSHA's estimate of covered employees is based on the discussion in the text. For example, as OSHA writes above: OSHA assumes for the purpose of its analysis that employers covered under the Contractor Guidance will conduct work at least some of the time in workplaces not covered under that Guidance and so are fully integrated into the scope of the ETS; and the employers and employees covered by the Healthcare ETS are also fully integrated into the scope of the ETS.

[30] Conditions are changing rapidly, and though many firms are planning to keep expanded telework to some extent, as the rate of vaccinated workers increases, there may be increased movement back to the workplace beyond what OSHA has estimated here.

Table IV.B.5. Summary of Covered Entities and Employees, COVID-19 ETS

NAICS	NAICS Description	Entities with 100+ Employees			
		Entities	Establishments	Total Employees	Covered Employees*1
0	**Total**	**263,879**	**1,858,935**	**102,673,913**	**84,194,885**
111	Crop Production	33,096	74,655	5,822,469	5,311,538
112	Animal Production and Aquaculture	16,985	38,314	2,988,147	2,725,932
113	Forestry and Logging	53	198	5,938	5,368
114	Fishing, Hunting and Trapping	8	21	972	887
115	Support Activities for Agriculture and Forestry	256	714	45,473	42,628
211	Oil and Gas Extraction	259	1,339	81,544	54,323
213	Support Activities for Mining	548	2,874	206,796	177,099
221	Utilities	842	13,136	594,213	457,268
236	Construction of Buildings	1,562	3,968	377,761	296,975
237	Heavy and Civil Engineering Construction	1,693	4,135	602,769	518,130
238	Specialty Trade Contractors	5,465	11,908	1,317,912	1,106,486
311	Food Manufacturing	2,649	5,899	1,283,687	1,198,905
312	Beverage and Tobacco Product Manufacturing	339	976	138,587	118,372
313	Textile Mills	291	448	73,287	66,475
314	Textile Product Mills	242	393	64,522	56,349
315	Apparel Manufacturing	216	256	43,856	37,266
316	Leather and Allied Product Manufacturing	60	88	16,240	13,401
321	Wood Product Manufacturing	1,037	2,637	258,244	233,721
322	Paper Manufacturing	712	2,033	299,184	267,712
323	Printing and Related Support Activities	857	1,942	238,106	177,505
324	Petroleum and Coal Products Manufacturing	295	1,369	96,415	83,198
325	Chemical Manufacturing	2,211	5,063	663,493	551,194
326	Plastics and Rubber Products Manufacturing	2,054	4,421	627,642	565,890
327	Nonmetallic Mineral Product Manufacturing	1,045	5,684	273,490	236,634
331	Primary Metal Manufacturing	916	1,609	322,169	294,607
332	Fabricated Metal Product Manufacturing	3,852	6,538	776,594	680,758
333	Machinery Manufacturing	2,727	4,324	748,064	614,838
334	Computer and Electronic Product Manufacturing	1,706	2,653	652,153	477,811
335	Electrical Equipment, Appliance, and Component Manufacturing	803	1,323	276,253	228,550
336	Transportation Equipment Manufacturing	1,953	3,560	1,413,486	1,239,323
337	Furniture and Related Product Manufacturing	719	1,095	230,143	203,844
339	Miscellaneous Manufacturing	1,074	2,149	341,544	265,877
423	Merchant Wholesalers, Durable Goods	8,988	68,595	2,072,944	1,385,610
424	Merchant Wholesalers, Nondurable Goods	5,669	32,910	1,588,892	1,063,719
425	Wholesale Electronic Markets and Agents and Brokers	342	1,753	149,629	77,323
441	Motor Vehicle and Parts Dealers	3,826	37,692	1,138,994	985,554
442	Furniture and Home Furnishings Stores	415	15,295	263,232	225,025
443	Electronics and Appliance Stores	239	10,035	209,975	182,586

Table IV.B.5. Summary of Covered Entities and Employees, COVID-19 ETS

NAICS	NAICS Description	Entities with 100+ Employees			
		Entities	Establishments	Total Employees	Covered Employees*1
444	Building Material and Garden Equipment and Supplies Dealers	1,192	22,265	890,976	781,239
445	Food and Beverage Stores	1,927	33,222	2,356,676	2,226,381
446	Health and Personal Care Stores	663	50,498	726,249	658,548
447	Gasoline Stations	1,332	41,559	524,523	503,976
448	Clothing and Clothing Accessories Stores	924	82,509	1,462,230	1,393,288
451	Sporting Goods, Hobby, Musical Instrument, and Book Stores	281	11,623	331,339	307,083
452	General Merchandise Stores	141	45,771	2,666,443	1,991,708
453	Miscellaneous Store Retailers	1,009	22,875	356,750	279,509
454	Nonstore Retailers	1,447	7,589	430,825	279,099
481	Air Transportation	284	2,115	452,001	412,795
482	Rail Transportation	8	8	182,819	162,922
483	Water Transportation	158	538	52,723	41,954
484	Truck Transportation	2,597	15,684	878,429	739,360
485	Transit and Ground Passenger Transportation	927	3,775	361,731	332,064
486	Pipeline Transportation	133	3,519	49,720	40,045
487	Scenic and Sightseeing Transportation	81	173	13,055	11,407
488	Support Activities for Transportation	1,428	11,178	482,778	345,888
491	Postal Service	22	324	5,725	5,246
492	Couriers and Messengers	195	6,232	582,624	541,677
493	Warehousing and Storage	2,585	10,555	849,269	772,759
511	Publishing Industries (except Internet)	1,477	8,440	802,903	557,875
512	Motion Picture and Sound Recording Industries	406	3,518	244,844	167,652
515	Broadcasting (except Internet)	336	3,503	216,126	150,029
517	Telecommunications	637	47,673	986,794	660,528
518	Data Processing, Hosting, and Related Services	1,203	7,615	428,143	305,191
519	Other Information Services	431	2,393	242,159	166,421
521	Monetary Authorities-Central Bank	12	58	19,738	14,064
522	Credit Intermediation and Related Activities	3,950	142,258	2,491,060	1,633,832
523	Securities, Commodity Contracts, and Other Financial Investments and Related Activities	1,761	39,199	657,382	373,616
524	Insurance Carriers and Related Activities	2,333	40,887	2,025,570	1,003,146
525	Funds, Trusts, and Other Financial Vehicles	32	43	1,148	597
531	Real Estate	3,619	58,080	670,589	466,656
532	Rental and Leasing Services	980	30,076	340,885	261,218
533	Lessors of Nonfinancial Intangible Assets (except Copyrighted Works)	240	432	24,333	12,725
541	Professional, Scientific, and Technical Services	14,480	96,947	5,041,154	3,074,578
551	Management of Companies and Enterprises	17,492	45,781	3,372,010	1,809,583
561	Administrative and Support Services	13,138	72,555	9,392,357	7,506,733
562	Waste Management and Remediation Services	820	7,387	261,091	224,482
611	Educational Services	15,228	30,172	7,796,496	7,194,705
621	Ambulatory Health Care Services	12,590	123,811	4,046,787	3,387,780

Table IV.B.5. Summary of Covered Entities and Employees, COVID-19 ETS

NAICS	NAICS Description	Entities with 100+ Employees			
		Entities	Establishments	Total Employees	Covered Employees*[1]
622	Hospitals	4,638	8,458	8,477,383	7,365,469
623	Nursing and Residential Care Facilities	9,953	55,269	3,012,595	2,702,195
624	Social Assistance	10,373	42,935	1,876,263	1,625,123
711	Performing Arts, Spectator Sports, and Related Industries	863	1,653	317,314	236,055
712	Museums, Historical Sites, and Similar Institutions	389	664	90,298	69,151
713	Amusement, Gambling, and Recreation Industries	2,743	12,532	1,025,842	912,667
721	Accommodation	2,312	13,016	1,506,093	1,341,571
722	Food Services and Drinking Places	11,586	164,442	5,872,006	5,771,927
811	Repair and Maintenance	1,926	16,142	328,743	280,374
812	Personal and Laundry Services	1,202	29,202	416,083	384,695
813	Religious, Grantmaking, Civic, Professional, and Similar Organizations	3,390	9,780	728,019	478,616

Sources: OSHA analysis based on SUSB (U.S. Census Bureau, 2019), QCEW (BLS, 2017), Agricultural Census (NASS, 2017), BLS OEWS (BLS, 2021a), BLS ORS (BLS, 2020), BLS CPS (BLS, 2021c), and (Dingel and Neiman, July, 2020).
*For instances where occupation data was not available at the 4-digit level from BLS, OSHA estimated teleworking for the 4-digit NAICS based on the average of reported data for other NAICS in the same 3-digit code.
[1]Derived by multiplying the total employees by the percent of employees covered by ETS in Table B-1

III. Baseline Vaccine Status for Covered Employees

To estimate the cost of the ETS, OSHA must first estimate the baseline vaccination status for the 84.2m covered employees (those who work for employers with 100 or more employees and are not otherwise excluded from coverage). OSHA recognizes that employees' current vaccination status continues to change on a daily basis. When specifying baseline vaccination rates, OSHA used the most recently available vaccination data from CDC, reflecting current conditions. For the remaining set of unvaccinated employees covered by the ETS, after accounting for baseline vaccinations, OSHA estimates the number of these employees who will be vaccinated and the number who will test under the ETS. OSHA's methodology for this analysis is detailed below.

a. Estimate the Current Vaccination Rate for Covered Employees

To estimate the current vaccinate rate for covered employees, OSHA obtained recent vaccination data by age group from the CDC COVID Data Tracker (CDC, October 4, 2021a).[31] For age groups covering 18–74 years old, these data include the number of people who are fully-vaccinated as well as the number of people of who have initiated their first shot in the past two weeks (relative to the October 4, 2021 data).[32] OSHA estimates the vaccination rate for each group (percent of total population in the age group who are vaccinated) based on the total number of people who are fully-vaccinated and had their first shot in the past two weeks, as a fraction of the population in each age group, obtained from the BLS Current Population Survey (CPS) (BLS, 2021d). Then, to estimate the overall average vaccination rate across age groups 18–74 years old, OSHA weighted each group based on the distribution of the labor force by age, also obtained from the BLS CPS (BLS, 2021d). As shown in Table IV.B.6, OSHA estimates an overall vaccination rate of 61.3 percent for covered employees (and 38.7 percent unvaccinated). The healthcare sector had an earlier push to get healthcare workers vaccinated and has a higher current rate, estimated to be 70 percent.[33]

[31] The data from the CDC website was retrieved on October 4, 2021.

[32] Age groups included: 18–24, 25–39, 40–49, 50–64, and 65–74. OSHA had not included the group 65–74 in the economic analysis of the Healthcare ETS this past spring because for the healthcare sector, using the population wide average of workers in this age bracket was felt would overcount the number of such workers in this sector. OSHA is including this group now that more of the other age populations have been vaccinated and those concerns are no longer as relevant. This ETS will therefore indicate that a slightly higher percentage of universe of covered employees is vaccinated than if that age group of 65–74 was excluded altogether, but it also increases the number of employees for which additional compliance costs are factored in. OSHA interprets the ultimate result as a more accurate reflection of the workplace and notes that more costs are included than if the age group had been excluded from the analysis.

[33] The agency takes a recent survey (Lazer et al., August 16, 2021) which breaks out rates for healthcare vaccination and non-healthcare, and rather than replacing the CDC base vaccination rate uses the CDC rate to make an adjustment upwards to the healthcare rate of 70 percent.

Table IV.B.6. Current Vaccination Rate for Covered Employees

Age Group	# Persons Fully Vaccinated	# Persons initiated vaccination in Last 14 Days	Population	Labor Force Population	Labor Force % Distribution	Vaccination Rate
18_24	14,561,608	375,202	28,721,000	18,125,000	12%	52.01%
25_39	35,120,448	842,480	66,219,000	54,114,000	35%	54.31%
40_49	24,269,765	409,905	39,631,000	32,547,000	21%	62.27%
50_64	43,093,957	505,140	62,386,000	42,447,000	27%	69.89%
65_74	25,442,283	358,394	32,388,000	8,626,000	6%	79.66%
					Average Vaccination Rate	**61.3%**
Source: CDC (October 4, 2021a), BLS (2021d)						

Based on the above, OSHA estimates that the 84.2m covered employees includes 52.5 million (62 percent) vaccinated employees and 31.7 million unvaccinated employees (38 percent).

b. Adjust Baseline Vaccination for Continuing Trends

OSHA adjusts the current vaccination rate to account for continuing trends in vaccinations among covered employees due to employers' continued implementation of vaccine mandates and other policies (described below), under the ETS. To make this adjustment, OSHA requires 1) further characterization of the set of unvaccinated employees in terms of their likelihood to receive the vaccine, and 2) specification of the extent of employer-mandated and other employer vaccination policies.

Based on vaccine confidence data from CDC (CDC, October 2021a), 13.8 percent of the population ''probably or definitely will not'' get the vaccine; hereafter referred to as ''vaccine-hesitant''. Since this group is by definition part of the currently unvaccinated, OSHA characterizes the currently unvaccinated (37.6 percent) as being comprised of those who are vaccine—hesitant (13.8 percent) and the remainder, who while unvaccinated, are not hesitant because they are not in the ''probably or definitely will not'' group (23.8 percent).

Among those who are vaccine-hesitant, OSHA estimates that 5 percent of covered employees (or about 36 percent of the vaccine-hesitant), are hesitant due to a religious (4 percent) or medical (1 percent) exemption. The remaining 8.8 percent include those who are vaccine-hesitant for other reasons. For the 4 percent estimate for religious exemptions, OSHA relies on data from Vermont, which removed its vaccine exemption for nonreligious personal beliefs in 2016 and saw the proportion of kindergarten students with a religious exemption rise to about 4 percent (Graham, September 15, 2021). In analyzing this issue, the agency also reviewed other religious exemption data concerning state workers in Oregon and Washington; the agency decided not to rely on these data because the Vermont data is a more accurate measure of the correct religious exemption rate, although the data does represent parents deciding on whether to claim an exemption for their child, not for themselves. This is because, unlike the Vermont data, the Oregon and Washington data contain workers that have applied, but not yet been accepted, for a religious exemption (O'Sullivan, September 18, 2021; KEZI News, September 25, 2021). In Oregon, 5 percent and in Washington 8 percent of the employees have requested accommodations though only a fraction so far have been accepted. However, the data are not inconsistent with the Vermont data even though the process in both Oregon and Washington are not yet complete. For the 1 percent estimate for medical exemptions, OSHA relied on the Household Pulse Survey (HPS) conducted by the U.S. Census (U.S. Census Bureau, 2021). In Table 6a of the Health Tables for Week 31, September 1, 2021 through September 13, 2021, about 1% of the US population said they would not get the vaccine because ''Doctor has not recommended it,'' and OSHA uses this response as a proxy for all medical conditions.[34]

Table IV.B.7 presents the number of employees in each vaccination category, which informs OSHA's subsequent estimates of which currently unvaccinated employees may be vaccinated by employer-mandates, vaccinated under the ETS, or tested under the ETS.

[34] Table 6a presents that 3,884,902 of the population will not take the vaccine because the ''doctor has not recommended it'' out of a total of 38,936,606 who will not get the vaccine for any reason. Medical reasons are then about 10% of the general population that will not get the vaccine, and the ones who won't get the vaccine are about 10% of the whole population, giving 1% (.10 * .10).

Table IV.B.7. Summary of Currently Unvaccinated Employees

Baseline Vaccination Status	Percent of Covered Employees	Number of Covered Employees
All Covered Employees	**100%**	**84,194,885**
Currently Vaccinated	**62.4%**	**52,510,781**
Unvaccinated	**37.6%**	**31,684,103**
Vaccine-Hesitant	13.8%	11,618,894
Medical exemption	1.0%	841,949
Religious exemption	4.0%	3,367,795
Hesitant for other reasons	8.8%	7,409,150
Unvaccinated but Not Vaccine-Hesitant	23.8%	20,065,209
Sources: OSHA analysis, CDC COVID Data Tracker (CDC, October 4, 2021a), BLS Current Population Survey (CPS) (BLS, 2021d), Household Pulse Survey (U.S. Census Bureau, 2021), New York Times (Graham, September 15, 2021)		

Next, OSHA estimates the number of currently unvaccinated employees that are likely to become vaccinated while the ETS is in effect, based on their employers' policies. Based on limited data on current vaccine mandate implementation and forecasts for future implementation (Mishra and Hartstein, August 23, 2021; ASU COVID–19 Diagnostic Commons, October 6, 2021), OSHA estimates that 25 percent of firms in scope currently have a mandate, and assumes that this will rise to 60 percent of employers after the ETS is in place. The baseline of 25 percent is based on recent surveys showing a range of approximately 13–45 percent of employers currently requiring or planning to require vaccination among employees (see Willis Towers Watson, June 23, 2021; Mishra and Hartstein, August 23, 2021; ASU COVID–19 Diagnostic Commons, October 6, 2021). Absent the ETS, OSHA assumes that the percentage of firms would remain 25 percent (with some measure of upward adjustment due to other federal vaccine mandates affecting select populations, as discussed above). To the extent more firms than OSHA estimates would mandate vaccination independent of the ETS and thereby increase the vaccination rate (again because of factors such as other federal vaccine mandates), then the agency's costs are overestimated because the agency's baseline vaccination rate is too low. The assumption of an increase from 25 to 60 percent is based on the same set of surveys that indicate that the share of employers who will mandate vaccinations after the ETS (including those that already mandate vaccinations) range from 25–75 percent, see above references. The agency also assumes that employees are distributed in the same proportion across employers with and without a vaccine mandate (e.g., if 60 percent of firms mandate vaccination, 60 percent of employees will be vaccinated due to the mandate (less those who remain unvaccinated due to religious or medical exemptions).

OSHA assumes that all unvaccinated employees subject to an employer mandate will be vaccinated under that employer mandate, except for those seeking a medical or religious exemption. For unvaccinated employees not subject to an employer mandate, OSHA assumes that they will also be vaccinated at their employer's request, except for employees who are vaccine-hesitant, which includes not only those who remain unvaccinated for medical and religious reasons, but also those who are hesitant for any other reason. OSHA carries through its assumptions and estimates into its total cost estimates. For example, OSHA estimates that the 25 percent of firms in scope that currently have a vaccination mandate will not need to implement a new written policy on vaccination in response to the ETS since they will already have implemented a policy that meets the requirements of the ETS.

In total, OSHA estimates that 27 percent of covered employees (22.7 million) will be vaccinated based on employer policies under the ETS; or 72 percent of covered employees who are currently unvaccinated. The resulting vaccination rate, adjusted for the ETS, is estimated based on the total of those who are currently vaccinated and those who will be vaccinated under employer policies, 89.4 percent as shown in Table IV.B.8. Calculations of this nature, while not discussed in more detail in this analysis, are contained fully in the spreadsheets supporting this analysis (OSHA, October 2021a).[35]

[35] OSHA notes that these estimates differ for employees covered by the Healthcare ETS. OSHA calculated these estimates separately because, as stated above, OSHA is only taking costs for these employees in the last four months of the assumed 6-month period while the ETS remains in effect. While OSHA does not describe in detail how it derived estimates for employees covered by the Healthcare ETS in this analysis, the derivation of those estimates run parallel to those described above. For more information, please see the spreadsheets supporting this analysis. (OSHA, October 2021a).

Table IV.B.8. Summary of Employee Vaccination Status under the ETS

Employee Vaccination Status under the ETS	Percent of All Covered Employees	Number of Covered Employees
Total Vaccinated, including ETS	**89.4%**	**75,262,549**
Vaccinated in the baseline, pre-ETS	62.4%	52,510,781
Vaccinated under the ETS	**27.0%**	**22,751,767**
Vaccinated under the ETS, Employer Mandates	**14.3%**	**12,050,322**
Vaccinated under the ETS, Voluntary Employer Policies	**12.7%**	**10,701,445**
Total Unvaccinated who Test with ETS	**7.5%**	**6,341,323**
Employer-Mandates, Vaccine exempt employees who test	1.8%	1,526,453
Voluntary Policies, Vaccine exempt employees who test	2.1%	1,744,518
Voluntary Policies, Other vaccine-hesitant employees who test	3.6%	3,070,352
Religious/medical exempt who Return to Telework	1.1%	938,773
Other hesitant who Return to Telework	2.0%	1,652,240
TOTAL COVERED EMPLOYEES	**100%**	**84,194,885**
Source: OSHA analysis		

From Table IV.B.8, OSHA estimates that approximately 75.3 million (89.4 percent) of covered employees will be vaccinated when the ETS is in full effect, and that approximately 8.9 million employees (10.6 percent, made up of approximately 6.3 million covered employees who will be tested for COVID under the ETS and approximately 2.6 million employees who return to telework (see next paragraph)) will remain unvaccinated. This final set of unvaccinated employees includes all employees not vaccinated because of religious or medical accommodations or medical contraindication, plus the portion of those who are vaccine-hesitant for any other reason, who were not vaccinated because their employer has opted for a voluntary vaccination policy.

From the above, OSHA estimates that about 5 percent of all covered employees will seek and receive religious or medical accommodations or exemption for medical contraindication. While the agency encourages employers to consider the most protective accommodations such as telework, which would prevent the employee from being exposed at work or from transmitting the virus at work, for cost analysis purposes the agency assumes these workers will largely be tested in order for their employers to comply with the ETS. Consistent with the overall average 22 percent of those who returned to work after teleworking earlier in the pandemic (see teleworking discussion above), OSHA assumes for this cost analysis that only 22 percent of workers needing a reasonable accommodation will return to full time telework as a reasonable accommodation. OSHA also assumes that the 78 percent remainder will follow the testing/masking protocols in the ETS as a reasonable accommodation.

For hesitant employees who will not seek a religious or medical accommodation, and who work in a firm with a testing option, the agency assumes as above that those who were teleworking before (again on average 22 percent) will return to telework rather than being tested.

c. Cost of Absenteeism to Employers

Even mild cases of Covid-19 can be costly to employers as they can induce productivity losses due to work absences, both among those infected and their close contacts who may be subject to quarantine requirements. While many workers were able to engage in telework in March-April 2020, several occupational groups deemed essential, including childcare workers, personal care aids, healthcare support occupations, and food processing workers, exhibited significantly higher rates of absenteeism during that period, which the authors attributed to some workers contracting COVID–19 (Groenewold et al., July 10, 2020). Absenteeism can also affect the productivity of workers who are present, similar to how turnover can impose costs on incumbent workers (Kuhn and Yu, April 2021).

In aggregate, productivity losses from absences can be costly, as evidenced by the economic losses from seasonal influenza. One estimate found that the United States loses 20.1 million days of economic productivity every year due to influenza, an ongoing loss equivalent to 80,400 full-time worker-years (Putri et al., June 22, 2018). Another recent study found that higher influenza vaccination rates result in both fewer deaths and significantly reduced illness-related work absences (White, 2021).

OSHA recognizes that absenteeism has been a problem. However, as explained in other sections of the preamble, the ETS vaccination and testing and face covering requirements are necessary to reduce the spread of COVID–19 in the workplace, which may in part reduce absenteeism. The ETS might in a limited sense also increase absenteeism because the rule requires employers to temporarily remove from the workplace any employee who receives a positive COVID–19 test or is diagnosed with COVID–19 by a licensed healthcare provider. However, this provision will also help to further reduce absenteeism because, when an

infected employee is promptly removed from the workplace, that can prevent one employee from infecting other employees in the workplace and potentially causing an outbreak or a super-spreader event. Thus, OSHA concludes that the ETS may, on net, help ameliorate absenteeism by reducing illnesses, but in any event will not increase absenteeism (see OSHA, October 2021c).

d. The Effect of Employee Turnover

One of the primary concerns among employers in imposing vaccination mandates is loss of staff, with 60 percent of employers selecting it as a concern with regard to mandating COVID–19 vaccination, according to one survey (Mishra and Hartstein, August 23, 2021).[36] To this end, employer vaccination mandates could lead to employee turnover; employees could either leave on their own volition or employers who have instituted strict vaccination policies may fire workers who are not vaccinated, or place them on unpaid leave.

On the other hand, there is countervailing evidence to suggest that employers who implement a vaccine mandate will be met with an influx of potential workers. Many employees would prefer a mandate in place, and would be more likely to stay with, or apply to, a firm that had a vaccine mandate in place. For example, although Inova health system in Northern Virginia, lost 89 workers for noncompliance with the system's vaccination mandate, that loss amounted to less than 0.5 percent of its workforce, (Portnoy, October 3, 2021), and, in any event, Inova's CEO stated that the vaccine mandate has helped with recruitment, and that its workers are concerned for their own safety and want to know they are working with vaccinated colleagues. This same article listed some other Virginia healthcare systems with higher rates of loss in connection with vaccine mandates. Valley Health terminated 1 percent of its employees, while Luminis Health had about 2 percent of its workers still unvaccinated at the time of its mandate deadline. As another example, although United Airlines had 593 employees (out of the company's 67,000 U.S. employees) who had not complied with the company's vaccination mandate at the end of September (a number that dropped below 240 employees by October 1), the company reported it has received 20,000 applications for 2,000 flight attendant positions, a much higher ratio than before the pandemic (Chokshi and Scheiber, October 2, 2021). In addition, one survey reports that among employee resignations due to COVID–19 workplace policies, 42 percent reported lack of workplace safety policies, 17 percent reported that existing workplace policies were not stringent enough, and only 39 percent reported overly restrictive workplace policies, suggesting that many employees will welcome vaccine mandates (ASU COVID–19 Diagnostic Commons, October 6, 2021).[37]

While employee turnover is a natural part of business in any industry, higher employee turnover rate than normal can have a direct impact on profit and revenue. The normal range of employee turnover differs widely by industry, with an average turnover rate of about 50 percent per year overall for the private sector.[38] For example, between 2016 and 2020, employee turnover ranged from 55 percent to 70 percent in the retail industry and from 40 percent to 60 percent in the transportation industry (the industry sectors with the highest employment).[39]

OSHA acknowledges that a vaccine mandate may result in increased employee turnover, but one recent survey [40] suggests it is very unlikely that this potential increase in employee turnover will exceed the ranges that industries have experienced over time. The survey, though limited because many respondents did not have mandates in place at that time, shows that there was no impact on turnover for 71 percent of those with mandates in place. Only 25 percent saw a slight increase in turnover (1 percent to 5 percent above normal) and only 4 percent saw a significant increase (more than 5 percent above normal). As such, OSHA does not anticipate that the potentially increased employee turnover attributable to vaccine mandates will be substantial enough to negate normal profit and revenue.

To this end, an important factor to consider in examining turnover in connection with vaccine mandates is the unquantified cost savings and other positive economic impacts accruing to employers that institute vaccine mandates. These include reduced absenteeism due to fewer COVID–19 illnesses and quarantines, as discussed above. Other positive economic impacts of a vaccine mandate are increased retail trade from customers that feel less at risk and better relations with suppliers and other business partners. These all would contribute to improved business and increased profits.

The existence of these cost savings and other positive economic impacts accruing to employers that comply with the ETS suggests that the actual net costs of the ETS could be much lower than the costs reported in this section of the economic analysis. As OSHA discusses above, OSHA has provided evidence to support its estimate that 25 percent of covered employers already voluntarily require that their employees be vaccinated and a much larger percentage are considering a vaccine mandate. This supports the conclusion that these businesses agree that doing so will ultimately save costs.

In addition, under the ETS, employers may implement a policy that allows for testing and face covering instead. Firms will have a tendency to self-select: If a large proportion of its work force has indicated concern about a vaccine mandate, the firm is more likely to choose the testing option to retain their workers. This is one factor that led the agency to estimate that approximately 40 percent of employers will allow employees to choose testing and face coverings in lieu of vaccination. To the extent employers are concerned about employee testing costs, employers can generally absorb testing costs or help employees reduce those costs through low-cost assistance such as employer proctoring of tests (even though that is not required by this ETS). Departure of personnel because of vaccine mandates is also likely to be less common when vaccine mandates are more prevalent across employers in a region or industry. One survey reports that 65 percent of employers state that actions of other companies in their industry are very, or at least moderately, important in deciding to mandate vaccination (Mishra and Hartstein, August 23, 2021).

Mandatory vaccinations for COVID–19 are still relatively new because vaccines only became available in quantities sufficient to support such mandates only about 6 months ago, and the FDA has only recently moved past emergency clearance to final clearance. While there is not an abundance of evidence about whether employees have actually left or joined an employer based on a vaccine mandate,

[36] This survey done in August, 2021, has 1,630 responses, reported by HR staff, attorneys, and executives. Described as being ''from a variety of industries,'' 83 percent of respondents were from companies with more than 100 employees.

[37] This August 2021 global survey (all results presented here are for the US only) has 1,143 responses. It covers 28 industries, including: Technology and Software, Business and Professional Services, Manufacturing, Construction, and Healthcare. Ninety percent of respondents were from companies with more than 100 employees.

[38] BLS (March 11, 2021).

[39] Id.

[40] Umland, October 13, 2021. This October 2021 survey has 1,059 total respondents, though only 365 have implemented a vaccination mandate and answered this turnover question.

particularly one with an alternative allowing for testing in lieu of vaccination, OSHA has examined the best available evidence it could locate in the timeline necessary to respond with urgency to the grave danger addressed in this ETS. Based on that, OSHA is persuaded that the net effect of the OSHA ETS on employee turnover will be relatively small, given the option for employers to implement a testing and face covering policy and the countervailing forces surrounding turnover that will limit those effects, as discussed above.

Finally, OSHA finds one line of evidence particularly persuasive because it involves data instead of polls: While different surveys may suggest different levels of worker intentions (joining or remaining with a safer employer versus leaving an employer to avoid vaccination),[41] the data suggests that the number of employees who actually leave an employer is much lower than the number who claimed they might: 1% to 3% or less actually leave, compared to the 48–50% who claimed they would.[42] As discussed earlier, this turnover number is well below the average turnover rate in most industries. Thus, OSHA concludes that whether or not the ETS proves helpful to recruitment efforts for some employers, it will not, on balance, add significant new costs to covered employers or threaten the economic feasibility of any industry during a six month period.

OSHA seeks comments on these estimates and conclusions, as well as further data that it could use to refine its estimates.

IV. Cost Analysis for COVID–19 Vaccination and Testing ETS, § 1910.501

In this section, OSHA provides estimates of the per-entity and total costs for the requirements of this ETS. Section 6(c)(3) of the OSH Act states that the Secretary will publish a final standard ''no later than six months after publication of the emergency standard.'' Costs are therefore estimated over a six-month time period. Note that the estimates are presented in this section at the 3-digit NAICS level, but the analysis was conducted at the 6-digit NAICS level and aggregated to the 3-digit level for presentation purposes. The 6-digit NAICS level data is accessible in the supporting spreadsheet. It should be noted that this analysis deals strictly with averages. For any given entity, actual costs may be higher or lower than the point estimate shown here, but using an average allows OSHA to evaluate feasibility by industry as required by the OSH Act. In addition, OSHA has limited data on many of the parameters needed in this analysis and has estimated them based on the available data, estimates for similar requirements for other OSHA standards, consultation with experts in other government agencies, and internal agency judgment where necessary. OSHA's estimates are therefore based on the best evidence available to the agency at the time this analysis of costs and feasibility was performed.

As mentioned above, OSHA estimates that approximately 264,000 entities have employees who will be subject to the requirements of the ETS, including approximately 84.2 million employees. Many ETS requirements result in labor burdens that are monetized using the labor rates described next.

a. Wage Rates

OSHA used occupation-specific wage rates from BLS 2020 OEWS data (BLS, 2021a). Within each affected 6-digit NAICS industry, OSHA calculated the employee-weighted average wage to be used in the analysis. OSHA estimated loaded wages using the BLS' Employer Cost for Employee Compensation data (BLS, 2021b), as well as OSHA's standard estimate for overhead of 17 percent times the base wage.

Costs are estimated using three labor rates for each NAICS industry: The average labor rate for all employees, the labor rate for General and Operations Managers (SOC code 11–1021), and the labor rate for Office Clerks, General (SOC 43–9060). Industry-specific wage rates are presented in Appendix C in the accompanying document in the docket, ''Vaccination and Testing ETS: Economic Profile and Cost Chapter Appendices (OSHA, October, 2021b).''

b. Rule Familiarization, Employer Policy on Vaccination, and Information Provided to Employees

ETS Requirements

Section 1910.501(d)(1) of the ETS specifies that the employer must establish and implement a written mandatory vaccination policy. The employer is exempted from the requirement in paragraph (d)(1) only if the employer establishes and implements a written policy allowing any employee not subject to a mandatory vaccination policy to either choose to be fully vaccinated against COVID–19 or to provide proof of regular testing for COVID–19 in accordance with paragraph (g) of the ETS and to wear a face covering in accordance with paragraph (i) of the ETS.[43]

In addition, under § 1910.501(j), information provided to employees, the ETS requires the employer to inform each employee, in a language and at a literacy level the employee understand about: (1) The requirements of the ETS as well as any employer policies and procedures established to implement the ETS; (2) COVID–19 vaccine efficacy, safety, and the benefits of being vaccinated; (3) the requirements of 29 CFR 1904.35(b)(1)(iv) and Section 11(c) of the OSH Act; and (4) the prohibitions of 18 U.S.C. 1001 and Section 17(g) of the OSH Act.

As stated, the ETS face covering requirements are contained in paragraph

[41] Two polls from June 2021, when the number of COVID–19 cases had dropped dramatically just before the Delta Variant led to a surge in cases, indicated that 50% of unvaccinated employees surveyed said that they would leave their job rather than accept a vaccination mandate from their employer. (KFF et al., June 30, 2021) (the same percentage also responded that ''The number of cases is so low that there is no need for more people to get the vaccine.''). A separate poll from the same time also stated that 48% of ''vaccine hesitant'' employees claimed they would quit their jobs rather than be vaccinated. (Barry et al., September 24, 2021—citing yet unpublished June 2021 poll). In a more recent poll, about 44% of workers said that they would consider leaving their jobs if they were forced to get vaccinated, while around 38% of workers would consider leaving their current employer if the organization did not enact a vaccine mandate. (Kelly August 12, 2021). Interestingly, in that survey there was a direct correlation between the age of the worker and the desire to have a vaccinated workplace: Younger workers, usually the most mobile portion of the workforce, had a much higher desire for a vaccinated workforce (50% of Generation Z employees, as compared to 33% of Baby Boomers).

[42] An article titled ''Unvaccinated Workers Say They'd Rather Quit Than Get a Shot, but Data Suggest Otherwise'' noted the 48%–50% threat to leave, but included hard data showing nothing close to those levels actually occurred: Houston Methodist Hospital required its 25,000 workers (including its 3,580 unvaccinated employees) to get a vaccine by June 7, and only 153 resigned or were fired (4% of the 3,580 unvaccinated employees; 0.6% of the total number of employees); other examples of the numbers of employees who left in response to their employers' mandatory vaccine policy involved 5 out of 527 (0.9%), 2 out of 250 (0.8%), 6 out of 260 (3%), and 125 out of 35,800 (0.3%). (Barry et al., September 24, 2021).

[43] Note to paragraph (d): Under federal law, including the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964, some workers may be entitled to a reasonable accommodation from their employer, absent undue hardship. If the worker requesting a reasonable accommodation cannot be vaccinated against COVID–19 and/or wear a face covering because of a disability, as defined by the ADA, or if the vaccination, testing, and/or wearing a face covering conflicts with the worker's sincerely held religious belief, practice or observance, the worker may be entitled to a reasonable accommodation. For more information about evaluating requests for these types of reasonable accommodations for disability or sincerely held religious belief, employers should consult the Equal Employment Opportunity Commission's regulations, guidance, and technical assistance including at: *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.*

(i) of the ETS. Under that paragraph, the employer, with certain exceptions specified in the ETS, must ensure that each employee who is not fully vaccinated wears a face covering when indoors and when occupying a vehicle with another person for work purposes. The ETS does not require, nor does it prohibit, the employer to pay for any costs associated with face coverings (although employer payment for face coverings may be required by other laws, regulations, or collective bargaining agreements or other collectively negotiated agreements). However, the employer must permit the employee to wear a respirator instead of a face covering whether required or not. In addition, the employer may provide respirators or face coverings to the employee, even if not required. In such circumstances, where the employer provides respirators, the employer must also comply with § 1910.504, *Mini respiratory protection program.*

OSHA estimates no costs associated with an employee voluntarily bringing in their own respirator to use instead of a face covering other than those costs that OSHA is estimating below in connection with 29 CFR 1910.501(j), information provided to employees. That section provides, again, that the employer must inform each employee, in a language and at a literacy level the employee understands about the requirements of the ETS as well as any employer policies and procedures established to implement the ETS. One policy the employer would need to establish to implement the ETS is a policy to comply with the requirements of 29 CFR 1910.504 when an employee voluntarily brings in their own respirator. Those requirements require only that the employer provide certain information to the employee (see 29 CFR 1910.504(c)).

OSHA is also estimating no costs in connection with the employer providing respirators to the employee. The ETS does not require the employer to provide respirators to employees. Therefore, any such provision is voluntary and not relevant to economic feasibility of this rule.

The face covering provisions in paragraph (i) contain several other requirements, none of which have costs associated with them.

Cost Analysis Assumptions

In this section, OSHA estimates the cost for establishing the employer policy on vaccination, providing required information to employees, and rule familiarization. OSHA assumes each entity will require an average one-time labor burden of 1 hour of management labor for rule familiarization. OSHA based this unit cost on that taken for rule familiarization in the Healthcare ETS (86 FR at 32496), but adjusted the time downward by a half-hour because this ETS is a simpler standard than the Healthcare ETS.

To establish a written policy in accordance with paragraph (d) of the ETS, OSHA assumes a one-time average labor burden of 5 hours of manager time per firm. OSHA bases this estimate on its cost estimates in the Healthcare ETS, where OSHA estimated that development of the COVID–19 Plan required by that standard would take between 5 and 40 hours (see 86 FR at 32496–32497). OSHA concludes that 5 hours is a reasonable estimate because the development of a written policy on vaccination will be much simpler than the development of the written COVID–19 Plan required by the Healthcare ETS (see 29 CFR 1910.502(c)).[44] OSHA notes, that like the Healthcare ETS (id.), the cost of implementing the plan for this ETS are included in the costs of implementing the corresponding requirements in the ETS, which are discussed below.

To provide information to employees in accordance with paragraph (j) of the ETS, OSHA assumes a one-time average labor burden per firm of 10 minutes of manager time. The agency expects activities like posting the information on a community board, mass emailing, etc., will satisfy this requirement.

The total cost for rule familiarization, establishing an employer policy on vaccination and providing required information to employees is calculated as the product of:

- One-time labor burden for rule familiarization and establishing a policy (a total of 6 hours of manager time per entity) plus a one-time labor burden for providing information to employees (10 minutes of manager time per entity);
- The labor rate for General and Operations Managers (SOC code 11–1021, NAICS-specific wages); and,
- The total number of covered entities.

Cost for Employer Policy on Vaccination and Information Provided to Employees

Costs per entity and total costs for employer policy on vaccination and information provided to employees are shown below in Table IV.B.9.

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[44] The estimates for the time to create the written vaccine policy plan under this ETS may differ from the time to create the various processes under the CMS rule published elsewhere in this issue of the **Federal Register** since the requirements of what is needed to be included in the plans differ. For example, the CMS plan requires a process for ensuring the implementation of additional precautions to mitigate the transmission and spread of COVID–19 while OSHA's vaccination policy requirements do not include this requirement.

Table IV.B.9. Employer Policy on Vaccination, Information Provided to Employees, and Rule Familiarization

NAICS 3	NAICS Description	Cost per Entity	Total Cost
	All Industry	**$566**	**$149,369,213**
111	Crop Production	$488	$11,567,901
112	Animal Production and Aquaculture	$488	$12,860,228
113	Forestry and Logging	$488	$25,852
114	Fishing, Hunting and Trapping	$488	$3,902
115	Support Activities for Agriculture and Forestry	$502	$128,465
211	Oil and Gas Extraction	$743	$192,411
213	Support Activities for Mining	$638	$349,364
221	Utilities	$640	$539,163
236	Construction of Buildings	$608	$950,407
237	Heavy and Civil Engineering Construction	$629	$1,065,167
238	Specialty Trade Contractors	$547	$2,988,530
311	Food Manufacturing	$584	$1,548,282
312	Beverage and Tobacco Product Manufacturing	$509	$172,512
313	Textile Mills	$610	$177,558
314	Textile Product Mills	$492	$119,184
315	Apparel Manufacturing	$483	$104,247
316	Leather and Allied Product Manufacturing	$568	$34,070
321	Wood Product Manufacturing	$527	$546,550
322	Paper Manufacturing	$653	$464,645
323	Printing and Related Support Activities	$547	$468,814
324	Petroleum and Coal Products Manufacturing	$709	$209,068
325	Chemical Manufacturing	$763	$1,686,303
326	Plastics and Rubber Products Manufacturing	$645	$1,324,528
327	Nonmetallic Mineral Product Manufacturing	$669	$699,290
331	Primary Metal Manufacturing	$667	$610,824
332	Fabricated Metal Product Manufacturing	$601	$2,314,763
333	Machinery Manufacturing	$701	$1,912,094
334	Computer and Electronic Product Manufacturing	$805	$1,372,646
335	Electrical Equipment, Appliance, and Component Manufacturing	$727	$583,727
336	Transportation Equipment Manufacturing	$679	$1,325,802
337	Furniture and Related Product Manufacturing	$651	$467,981
339	Miscellaneous Manufacturing	$631	$677,615
423	Merchant Wholesalers, Durable Goods	$591	$5,315,935
424	Merchant Wholesalers, Nondurable Goods	$596	$3,379,532
425	Wholesale Electronic Markets and Agents and Brokers	$642	$219,545
441	Motor Vehicle and Parts Dealers	$609	$2,329,166
442	Furniture and Home Furnishings Stores	$421	$174,541
443	Electronics and Appliance Stores	$363	$86,649
444	Building Material and Garden Equipment and Supplies Dealers	$401	$477,583
445	Food and Beverage Stores	$346	$667,288
446	Health and Personal Care Stores	$396	$262,639
447	Gasoline Stations	$302	$402,522
448	Clothing and Clothing Accessories Stores	$403	$372,696
451	Sporting Goods, Hobby, Musical Instrument, and Book Stores	$372	$104,434
452	General Merchandise Stores	$443	$62,519
453	Miscellaneous Store Retailers	$439	$443,175
454	Nonstore Retailers	$596	$862,946
481	Air Transportation	$638	$181,108

NAICS 3	NAICS Description	Cost per Entity	Total Cost
482	Rail Transportation	$619	$4,949
483	Water Transportation	$634	$100,204
484	Truck Transportation	$543	$1,409,505
485	Transit and Ground Passenger Transportation	$482	$446,817
486	Pipeline Transportation	$524	$69,691
487	Scenic and Sightseeing Transportation	$444	$35,984
488	Support Activities for Transportation	$552	$787,947
491	Postal Service	$532	$11,952
492	Couriers and Messengers	$404	$78,847
493	Warehousing and Storage	$543	$1,404,418
511	Publishing Industries (except Internet)	$697	$1,028,823
512	Motion Picture and Sound Recording Industries	$621	$252,163
515	Broadcasting (except Internet)	$637	$214,198
517	Telecommunications	$697	$443,865
518	Data Processing, Hosting, and Related Services	$738	$888,047
519	Other Information Services	$763	$328,677
521	Monetary Authorities-Central Bank	$803	$9,637
522	Credit Intermediation and Related Activities	$662	$2,613,092
523	Securities, Commodity Contracts, and Other Financial Investments and Related Activities	$783	$1,378,210
524	Insurance Carriers and Related Activities	$732	$1,706,718
525	Funds, Trusts, and Other Financial Vehicles	$804	$25,740
531	Real Estate	$584	$2,113,926
532	Rental and Leasing Services	$563	$551,823
533	Lessors of Nonfinancial Intangible Assets (except Copyrighted Works)	$673	$161,605
541	Professional, Scientific, and Technical Services	$749	$10,849,802
551	Management of Companies and Enterprises	$750	$13,119,146
561	Administrative and Support Services	$549	$7,212,244
562	Waste Management and Remediation Services	$514	$421,606
611	Educational Services	$603	$9,181,242
624	Social Assistance	$552	$6,952,935
711	Performing Arts, Spectator Sports, and Related Industries	$669	$3,103,079
712	Museums, Historical Sites, and Similar Institutions	$483	$4,805,434
713	Amusement, Gambling, and Recreation Industries	$426	$4,419,467
721	Accommodation	$516	$445,735
722	Food Services and Drinking Places	$484	$188,137
811	Repair and Maintenance	$420	$1,153,298
812	Personal and Laundry Services	$452	$1,045,225
813	Religious, Grantmaking, Civic, Professional, and Similar Organizations	$379	$4,393,360
Sources: OSHA analysis, BLS 2020 OEWS data (BLS, 2021a), BLS Employer Cost of Compensation (BLS, 2021b)			

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c. Determining Employee Vaccination Status

ETS Requirements

Under § 1910.501(e):

Paragraph (e)(1). The employer must determine the vaccination status of each employee. This determination must include whether the employee is fully vaccinated, which is 2 weeks after the full required vaccine course is completed.

Paragraph (e)(2). The employer must require each vaccinated employee to provide acceptable proof of vaccination status, including whether they are fully or partially vaccinated. Acceptable proof of vaccination status is:

- The record of immunization from a health care provider or pharmacy;
- A copy of the COVID–19 Vaccination Record Card;
- A copy of medical records documenting the vaccination;
- A copy of immunization records from a public health, state, or tribal immunization information system; or

• A copy of any other official documentation that contains the type of vaccine administered, date(s) of administration, and the name of the health care professional(s) or clinic site(s) administering the vaccine(s).

In instances where an employee is unable to produce acceptable proof of vaccination, per above, a signed and dated statement by the employee, subject to criminal penalties for knowingly providing false information:

• Attesting to their vaccination status (fully vaccinated or partially vaccinated); and

• Attesting that they have lost and are otherwise unable to produce proof required by the ETS.

Paragraph (e)(3). Any employee who does not provide one of the acceptable forms of proof of vaccination status in paragraph (e)(2) of the ETS to the employer must be treated as not fully vaccinated for the purpose of the ETS.

Paragraph (e)(4). The employer must maintain a record of each employee's vaccination status and must preserve acceptable proof of vaccination for each employee who is fully or partially vaccinated. The employer must maintain a roster of each employee's vaccination status. These records and roster are considered to be employee medical records and must be maintained as such records in accordance with 29 CFR 1910.1020 and must not be disclosed except as required or authorized by the ETS or other federal law. These records and roster are not subject to the retention requirements of 29 CFR 1910.1020(d)(1)(i) but must be maintained and preserved while the ETS remains in effect.

Paragraph (e)(5). Finally, when an employer has ascertained employee vaccination status prior to the effective date of this section through another form of attestation or proof, and retained records of that ascertainment, the employer is exempt from the requirements in paragraphs (e)(1)–(e)(3) only for each employee whose fully vaccinated status has been documented prior to the effective date of this section. For purposes of paragraph (e)(4), the employer's records of ascertainment of vaccination status for each such person constitute acceptable proof of vaccination.

The full costs for these provisions are taken under the costs for recordkeeping, discussed below, because determining vaccination status, providing acceptable proof of vaccination status, and creating and maintaining a roster of each employee's vaccination status will be part and parcel of the recordkeeping process.

d. Employer Support for Employee Vaccination

ETS Requirements

Under 29 CFR 1910.501(f):

The employer must support COVID–19 vaccination by providing:

• Time for vaccination. The employer must: (i) Provide a reasonable amount of time to each employee for each of their primary vaccination series dose(s); and (ii) provide up to 4 hours paid time, including travel time, at the employee's regular rate of pay for this purpose.

• Time for recovery. The employer must provide reasonable time and paid sick leave to recover from side effects experienced following any primary vaccination series dose to each employee for each dose.

Under the ETS, fully vaccinated means (i) a person's status 2 weeks after completing primary vaccination with a COVID–19 vaccine with, if applicable, at least the minimum recommended interval between doses in accordance with the approval, authorization, or listing that is: (A) Approved or authorized for emergency use by the FDA; (B) listed for emergency use by the World Health Organization (WHO); or (C) administered as part of a clinical trial at a U.S. site, if the recipient is documented to have primary vaccination with the ''active'' (not placebo) COVID–19 vaccine candidate, for which vaccine efficacy has been independently confirmed (e.g., by a data and safety monitoring board), or if the clinical trial participant from the U.S. site had received a COVID–19 vaccine that is neither approved nor authorized for use by FDA but is listed for emergency use by WHO; or (ii) a person's status 2 weeks after receiving the second dose of any combination of two doses of a COVID–19 vaccine that is approved or authorized by the FDA, or listed as a two-dose series by the WHO (i.e., heterologous primary series of such vaccines, receiving doses of different COVID–19 vaccines as part of one primary series). The second dose of the series must not be received earlier than 17 days (21 days with a 4-day grace period) after the first dose.

Cost Analysis Assumptions

OSHA assumes there will be no costs to employers or employees associated with the vaccine itself.[45] However, to provide support for vaccination of employees, OSHA estimates that it will take an average of 15 minutes of travel time, each way, per employee to travel to a vaccination site (for a total of 30 minutes). OSHA then estimates 5 minutes to wait, fill out any necessary paperwork, and receive the shot, and a post-shot wait time of 20 minutes, per employee. Some firms, particularly larger ones, will find it cheaper to have vaccines administered on site. They may have an on-site health clinic or may hire a 3rd party purveyor to come to the facility.[46] This will minimize travel and also allow the companies to mitigate some of the logistical issues that may be preventing employees from receiving a vaccine (finding a convenient appointment time, etc.). OSHA estimates that 10 percent of firms with employees between 100 to 500 employees will select this option, while, given decreased average costs associated with economies of scale, 25 percent of firms with over 500 employees will select this option. OSHA was unable to obtain an estimate of the cost savings associated with on-site vaccination in the time allotted to issue this emergency standard, so it is assuming that the costs for off-site vaccination are the same as the costs for on-site vaccination. This results in a likely over-estimate of costs given that the entities that choose the on-site option will do so as a cost-saving measure.

In OSHA's cost analysis, OSHA assumes that all employees will be vaccinated during working hours and employers would adjust the employee work schedule to ensure that the employee would not become eligible for overtime pay as a result of the vaccination time. However, it should be noted that, if an employee chooses to receive the vaccine outside of work hours, OSHA does not require employers to grant paid time to the employee for the time spent receiving the vaccine during non-work hours (although other laws may include additional requirements for employers, such as those addressing reasonable accommodations or exemptions). OSHA's analysis may be an overestimate as it reflects an assumption that all vaccinations are received during work hours.

CDC data indicated that 5 percent of employees vaccinated have received the Johnson & Johnson vaccine, and 95 percent have received either Pfizer or Moderna (CDC, October 2021b). OSHA applies the same allocation to employees being vaccinated under the ETS. For those receiving Pfizer or Moderna, the labor burden outlined

[45] While there may be some administrative costs borne by the government, such costs are not germane to this analysis of whether the ETS is economically feasible for covered employers.

[46] Prior to the effective date of this rule, some companies offered on-site vaccination according to a limited survey. (Willis Towers Watson, June 23, 2021). See also CDC on creating an on-site program (CDC, March 25, 2021; CDC, October 4, 2021b).

above occurs twice, since vaccination requires two shots.

The employer must provide reasonable time and paid sick leave to recover from side effects experienced following any vaccination dose to each employee for each vaccination dose. Employers may require employees to use paid sick leave benefits otherwise provided by the employer to offset these costs, if available. The average amount of time off an employee may need for side effects while receiving the vaccine doses necessary to achieve full vaccination (one or two doses, depending on the vaccine) depends on several factors. First, the percentage of people who will have side effects that are severe enough to require time. Second, the average time duration for those who have such a severe reaction. For estimates of these parameters OSHA is using a recent study (Levi et al., September 29, 2021) which surveyed workers at a state-wide health care system who had been vaccinated. The study found that, for the first dose, 4.9% needed administrative leave, with an average length of absence of 1.66 days. For the second dose, 19.79% needed leave and their average length of absence was 1.39 days. Together, the average time on leave is .36 days (.049 * 1.66 + .1979 * 1.39) for a person receiving two doses, which reflects the fact that many people who receive the vaccine do not have any side effects for either dose while others have more severe side effects.

In order to determine the amount of paid sick leave that would be available to employees, OSHA relied on data from BLS (BLS, 2021e). BLS estimates that for civilian workers in establishments with 100+ employees, 88% have access to paid sick leave (Table 33). BLS states that the average number of paid sick leave available is 9 days (Table 36). Because there is the same number of days across all levels of employee tenure (1 year, 5 years, 10 years, and 20 years), OSHA used 9 days for all covered employees. The agency assumes that 75% of the available paid sick leave has been used by the current 4th quarter of the calendar year. So the average number of days available is 1.98 days: 9 (days) * 88% (employees with available paid sick leave) * 25% (amount of leave remaining in the year) = 1.98 days available. Given that the average overall time out due to side effects is 0.36 days (see above), OSHA concludes that, on average, employees should have sufficient existing paid sick leave available to cover the time needed as a result of vaccine-related side effects. As a result, OSHA is taking no costs to employers in connection with the ETS's requirement to provide time for recovery from vaccination (except as provided below), as these costs will have been incurred by the employer independent of the ETS.

While this analysis is entirely consistent with OSHA's standard procedure of strictly using averages in cost analysis, it nonetheless masks some significant effects resulting from the time for recovery requirements. From the BLS data, OSHA knows there are 12% of establishments that have 100+ employees and do not provide paid sick leave. Correspondingly, there is a group of entities with no paid sick leave that will obviously incur costs that result directly from these requirements. In addition, some employees may not have, or some other entities may not offer, sufficient paid sick leave to cover these costs.

To account for the 12 percent of firms that do not offer paid sick leave, the agency uses the above estimate of average days for two doses, 0.36 days, and multiplies the average employee wage by NAICS to calculate the cost per employee. Since OSHA does not know which firms make up the 12 percent, the agency spreads this total cost across all firms by employee. Since firms without any sick leave are likely to be lower-wage firms, this will likely lead to a cost overestimate.

Therefore, the total cost for paid time off for vaccination is based on the costs for providing paid sick leave for the 12 percent of firms that do not offer paid sick leave and:

- Travel time per employee of covered firms of 15 minutes each way per vaccination dose (total of 30 minutes).
- Pre-shot wait time per employee of covered firms of 5 minutes per vaccination dose.
- Post-shot wait time per employee of covered firms of 20 minutes per vaccination dose.[47]
- The average labor rate for employees (NAICS-specific wages).
- Total number of employees at covered firms getting vaccinated due to the ETS with the Johnson & Johnson vaccine.
- Total number of employees at covered firms getting vaccinated due to the ETS with the Pfizer and Moderna vaccines, multiplied by two to account for two shots.

Cost for Support for Employee Vaccination

Costs per firm and total costs for vaccination are shown below in Table IV.B.10.

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[47] According to the CDC, people with allergies require a wait time of 30 minutes, but they are a small group, and, in any event, the CDC recommends that routine wait time is 15 minutes, so the agency considers that its average of 20 minutes is probably an overestimate. (See CDC, October 4, 2021a; CDC, March 3,2021.)

Table IV.B.10. Support for Employee Vaccination

NAICS 3	NAICS Description	Vaccine Administration Cost		Paid-Time-Off for Vaccine Side-Effects		Total Vaccine Cost	
		Cost per Firm	Total Cost	Cost per Firm	Total Cost	Cost per Firm	Total Cost
	All Industry	**$5,986**	**$1,579,580,408**	**$1,256**	**$331,315,843**	**$7,242**	**$1,910,896,252**
111	Crop Production	$2,833	$67,181,467	$575	$13,625,126	$3,407	$80,806,593
112	Animal Production and Aquaculture	$2,833	$74,686,751	$575	$15,147,279	$3,407	$89,834,030
113	Forestry and Logging	$1,693	$89,726	$363	$19,244	$2,056	$108,970
114	Fishing, Hunting and Trapping	$1,956	$15,651	$397	$3,174	$2,353	$18,825
115	Support Activities for Agriculture and Forestry	$2,077	$531,738	$433	$110,873	$2,510	$642,611
211	Oil and Gas Extraction	$7,219	$1,869,832	$1,535	$397,458	$8,754	$2,267,290
213	Support Activities for Mining	$6,971	$3,820,273	$1,460	$800,110	$8,431	$4,620,383
221	Utilities	$16,379	$13,788,406	$3,469	$2,920,645	$19,849	$16,709,050
236	Construction of Buildings	$4,536	$7,084,919	$942	$1,470,980	$5,478	$8,555,899
237	Heavy and Civil Engineering Construction	$6,678	$11,305,838	$1,386	$2,346,673	$8,064	$13,652,511
238	Specialty Trade Contractors	$4,219	$23,055,535	$867	$4,739,252	$5,086	$27,794,787
311	Food Manufacturing	$6,615	$17,523,367	$1,398	$3,704,410	$8,014	$21,227,778
312	Beverage and Tobacco Product Manufacturing	$6,108	$2,070,576	$1,282	$434,571	$7,390	$2,505,147
313	Textile Mills	$3,403	$990,312	$719	$209,158	$4,122	$1,199,470
314	Textile Product Mills	$3,281	$793,931	$688	$166,438	$3,968	$960,370
315	Apparel Manufacturing	$2,601	$561,851	$537	$115,986	$3,138	$677,836
316	Leather and Allied Product Manufacturing	$3,296	$197,785	$693	$41,604	$3,990	$239,389
321	Wood Product Manufacturing	$3,348	$3,471,552	$700	$725,624	$4,047	$4,197,175
322	Paper Manufacturing	$7,104	$5,057,703	$1,503	$1,070,265	$8,607	$6,127,969
323	Printing and Related Support Activities	$3,552	$3,043,852	$738	$632,498	$4,290	$3,676,349
324	Petroleum and Coal Products Manufacturing	$7,752	$2,286,758	$1,664	$490,914	$9,416	$2,777,673
325	Chemical Manufacturing	$6,503	$14,377,919	$1,382	$3,055,175	$7,885	$17,433,095
326	Plastics and Rubber Products Manufacturing	$4,617	$9,483,784	$972	$1,995,996	$5,589	$11,479,780
327	Nonmetallic Mineral Product Manufacturing	$4,919	$5,140,695	$1,038	$1,084,668	$5,957	$6,225,363
331	Primary Metal Manufacturing	$5,949	$5,449,397	$1,263	$1,156,901	$7,212	$6,606,298
332	Fabricated Metal Product Manufacturing	$3,087	$11,890,030	$647	$2,493,922	$3,734	$14,383,952
333	Machinery Manufacturing	$5,082	$13,858,181	$1,074	$2,929,438	$6,156	$16,787,619
334	Computer and Electronic Product Manufacturing	$8,278	$14,122,918	$1,761	$3,004,199	$10,039	$17,127,117
335	Electrical Equipment, Appliance, and Component Manufacturing	$5,709	$4,584,456	$1,216	$976,533	$6,925	$5,560,988
336	Transportation Equipment Manufacturing	$13,591	$26,542,815	$2,891	$5,645,305	$16,481	$32,188,120

NAICS 3	NAICS Description	Vaccine Administration Cost		Paid-Time-Off for Vaccine Side-Effects		Total Vaccine Cost	
		Cost per Firm	Total Cost	Cost per Firm	Total Cost	Cost per Firm	Total Cost
337	Furniture and Related Product Manufacturing	$4,323	$3,108,499	$901	$647,680	$5,224	$3,756,179
339	Miscellaneous Manufacturing	$5,005	$5,375,711	$1,053	$1,131,336	$6,059	$6,507,047
423	Merchant Wholesalers, Durable Goods	$3,488	$31,354,015	$731	$6,568,296	$4,219	$37,922,312
424	Merchant Wholesalers, Nondurable Goods	$3,566	$20,216,604	$746	$4,229,315	$4,312	$24,445,919
425	Wholesale Electronic Markets and Agents and Brokers	$5,834	$1,995,111	$1,218	$416,506	$7,052	$2,411,617
441	Motor Vehicle and Parts Dealers	$4,271	$16,339,598	$876	$3,350,461	$5,146	$19,690,058
442	Furniture and Home Furnishings Stores	$7,654	$3,176,394	$1,606	$666,527	$9,260	$3,842,920
443	Electronics and Appliance Stores	$11,543	$2,758,856	$2,401	$573,783	$13,944	$3,332,639
444	Building Material and Garden Equipment and Supplies Dealers	$8,714	$10,386,964	$1,805	$2,151,828	$10,519	$12,538,791
445	Food and Beverage Stores	$13,183	$25,404,044	$2,729	$5,258,225	$15,912	$30,662,269
446	Health and Personal Care Stores	$14,675	$9,729,400	$3,127	$2,073,398	$17,802	$11,802,798
447	Gasoline Stations	$3,755	$5,001,552	$780	$1,038,480	$4,535	$6,040,032
448	Clothing and Clothing Accessories Stores	$17,590	$16,253,205	$3,721	$3,438,495	$21,311	$19,691,700
451	Sporting Goods, Hobby, Musical Instrument, and Book Stores	$12,509	$3,515,167	$2,616	$735,212	$15,126	$4,250,379
452	General Merchandise Stores	$194,153	$27,375,523	$42,792	$6,033,656	$236,945	$33,409,178
453	Miscellaneous Store Retailers	$3,878	$3,912,708	$809	$816,488	$4,687	$4,729,196
454	Nonstore Retailers	$4,046	$5,854,060	$853	$1,233,752	$4,898	$7,087,812
481	Air Transportation	$42,231	$11,993,626	$8,996	$2,554,740	$51,227	$14,548,366
482	Rail Transportation	$513,849	$4,110,795	$104,214	$833,714	$618,064	$4,944,509
483	Water Transportation	$6,161	$973,423	$1,310	$207,014	$7,471	$1,180,437
484	Truck Transportation	$5,777	$15,002,604	$1,211	$3,143,797	$6,987	$18,146,401
485	Transit and Ground Passenger Transportation	$5,172	$4,794,222	$1,073	$994,672	$6,245	$5,788,894
486	Pipeline Transportation	$8,133	$1,081,664	$1,790	$238,023	$9,922	$1,319,688
487	Scenic and Sightseeing Transportation	$2,202	$178,339	$461	$37,356	$2,663	$215,695
488	Support Activities for Transportation	$4,650	$6,640,538	$986	$1,407,853	$5,636	$8,048,391
491	Postal Service	$4,781	$107,477	$970	$21,798	$5,750	$129,275
492	Couriers and Messengers	$46,588	$9,084,734	$9,694	$1,890,395	$56,283	$10,975,129
493	Warehousing and Storage	$4,374	$11,305,759	$932	$2,410,060	$5,306	$13,715,818
511	Publishing Industries (except Internet)	$13,446	$19,859,819	$2,820	$4,164,965	$16,266	$24,024,785
512	Motion Picture and Sound Recording Industries	$10,509	$4,266,791	$2,189	$888,750	$12,698	$5,155,540
515	Broadcasting (except Internet)	$11,872	$3,988,882	$2,499	$839,502	$14,370	$4,828,384
517	Telecommunications	$31,402	$20,002,816	$6,561	$4,179,313	$37,963	$24,182,129

NAICS 3	NAICS Description	Vaccine Administration Cost		Paid-Time-Off for Vaccine Side-Effects		Total Vaccine Cost	
		Cost per Firm	Total Cost	Cost per Firm	Total Cost	Cost per Firm	Total Cost
518	Data Processing, Hosting, and Related Services	$8,353	$10,049,205	$1,765	$2,123,795	$10,119	$12,173,000
519	Other Information Services	$13,191	$5,685,115	$2,780	$1,198,340	$15,971	$6,883,455
521	Monetary Authorities-Central Bank	$42,411	$508,934	$9,416	$112,996	$51,828	$621,930
522	Credit Intermediation and Related Activities	$10,473	$41,368,383	$2,179	$8,605,082	$12,652	$49,973,465
523	Securities, Commodity Contracts, and Other Financial Investments and Related Activities	$6,315	$11,120,669	$1,343	$2,365,688	$7,658	$13,486,357
524	Insurance Carriers and Related Activities	$11,366	$26,517,791	$2,425	$5,657,214	$13,791	$32,175,005
525	Funds, Trusts, and Other Financial Vehicles	$654	$20,930	$139	$4,460	$793	$25,390
531	Real Estate	$2,973	$10,759,172	$619	$2,240,979	$3,592	$13,000,151
532	Rental and Leasing Services	$5,175	$5,071,063	$1,089	$1,067,380	$6,264	$6,138,444
533	Lessors of Nonfinancial Intangible Assets (except Copyrighted Works)	$1,568	$376,385	$337	$80,792	$1,905	$457,177
541	Professional, Scientific, and Technical Services	$6,842	$99,074,392	$1,436	$20,787,377	$8,278	$119,861,769
551	Management of Companies and Enterprises	$3,260	$57,025,453	$690	$12,072,397	$3,950	$69,097,850
561	Administrative and Support Services	$8,646	$113,587,118	$1,814	$23,826,990	$10,459	$137,414,108
562	Waste Management and Remediation Services	$4,972	$4,078,939	$1,043	$855,705	$6,015	$4,934,643
611	Educational Services	$11,094	$168,935,399	$2,352	$35,821,592	$13,447	$204,756,991
624	Social Assistance	$5,236	$65,919,369	$1,098	$13,828,307	$6,334	$79,747,676
711	Performing Arts, Spectator Sports, and Related Industries	$31,037	$143,960,902	$6,613	$30,675,269	$37,651	$174,636,171
712	Museums, Historical Sites, and Similar Institutions	$3,516	$34,997,577	$728	$7,245,346	$4,244	$42,242,923
713	Amusement, Gambling, and Recreation Industries	$2,019	$20,939,355	$418	$4,337,995	$2,437	$25,277,350
721	Accommodation	$5,076	$4,380,579	$1,061	$916,022	$6,137	$5,296,601
722	Food Services and Drinking Places	$3,006	$1,169,323	$619	$240,663	$3,625	$1,409,986
811	Repair and Maintenance	$4,237	$11,622,911	$881	$2,415,571	$5,118	$14,038,483
812	Personal and Laundry Services	$6,482	$14,985,584	$1,356	$3,135,374	$7,838	$18,120,958
813	Religious, Grantmaking, Civic, Professional, and Similar Organizations	$5,028	$58,254,035	$1,039	$12,043,048	$6,067	$70,297,082
Sources: OSHA analysis, BLS 2020 OEWS data (BLS, 2021a), BLS Employer Cost of Compensation (BLS, 2021b), BLS sick leave data (BLS, 2021e), CDC COVID Data Tracker (CDC, October 4, 2021a), Levi et al. (September 29, 2021)							

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e. COVID–19 Testing for Employees Who Are Not Fully Vaccinated

ETS Requirements

Section 1910.501(g)(1) of the ETS requires the employer to ensure that each employee who is not fully vaccinated do the following:

An employee who reports at least once every 7 days to a workplace where other individuals, such as coworkers or customers, are present:

- Must be tested for COVID–19 at least once every 7 days; and
- Must provide documentation of the most recent COVID–19 test result to the employer no later than the 7th day following the date on which the employee last provided a test result.

An employee who does not report during a period of 7 or more days to a workplace where other individuals, such as coworkers or customers, are present (*e.g.,* teleworking for two weeks prior to reporting to a workplace with others):

- Must be tested for COVID–19 within 7 days prior to returning to the workplace; and
- Must provide documentation of that test result to the employer upon return to the workplace.

Furthermore, if an employee does not provide documentation of a COVID–19 test result as required by paragraph (g)(1) of the ETS, the employer must keep that employee removed from the workplace until they provide a test result. In addition, when an employee has received a positive COVID–19 test, or has been diagnosed with COVID–19 by a licensed healthcare provider, the employer must not require that employee to undergo COVID–19 testing as required under paragraph (g) of this section for 90 days following the date of their positive test or diagnosis. Finally, the employer must maintain a record of each test result provided by each employee under paragraph (g)(1) of this section or obtained during tests conducted by the employer. These records are considered to be employee medical records and must be maintained as such records in accordance with 29 CFR 1910.1020 and must not be disclosed except as required or authorized by this section or other federal law. These records are not subject to the retention requirements of 29 CFR 1910.1020(d)(1)(i) but must be maintained and preserved while this section remains in effect.

OSHA addresses the costs associated with testing in the next section. The remaining costs required by paragraph (g) are taken under the costs for recordkeeping, discussed below, because providing documentation of test results to the employer will be part and parcel of the recordkeeping process.

Employees who are partially vaccinated are also required to be tested weekly until they are fully vaccinated. Those receiving the J&J vaccine will require two weeks of testing after the single shot, employees who received the Pfizer-BioNTech Vaccine will require 5 weeks of testing (3 weeks between shots and 2 weeks following the second shot), and Moderna recipients require 6 weeks of testing (4 weeks between shots and 2 weeks following the second shot) (CDC, October 4, 2021b). Notwithstanding this, in the agency's total cost estimate OSHA accounts for the fact that employers need not comply with the requirements of this section in paragraph (g) by 60 days after the rule's effective date, and that employees who have completed the entire primary vaccination series by that date do not have to be tested, even if they have not yet completed the 2 week waiting period.

There is no requirement in the rule that the employer pay for this testing so these testing-related costs are not included in the main analysis (although, as discussed below OSHA takes into account costs for testing in connection with the ETS's recordkeeping requirements). The agency estimates that 6.3 million weekly tests will need to be given due to this ETS (see Table IV.B.8). This 6.3 million is likely an overestimate of new costs because it encompasses tests for employees who were already required to conduct testing by their employers prior to this ETS.

OSHA also notes that its cost estimates for testing do not take into account the 90-day break in testing that occurs following the date of a positive test or diagnosis. OSHA's cost estimates are also potentially overcounting costs in that OSHA does not take into account that not all employees for whom testing is required will report at least once every 7 days to a workplace where other individuals, such as coworkers or customers, are present. Thus, OSHA's estimate assumes that employees for whom testing is required will need to be tested at least once every 7 days and not less frequently as will often be the case.

OSHA notes, in addition, that there are no costs associated with paragraph (g)'s removal provision. The ETS does not require the employer to provide paid time off to any employee for removal as a result of the employee's refusal/failure to provide documentation of a COVID–19 test result as required by paragraph (g)(1) of the ETS.

Finally, OSHA notes that a COVID–19 test under the ETS is a test for SARS–CoV–2 that is: (i) Cleared, approved, or authorized, including in an Emergency Use Authorization (EUA), by the FDA to detect current infection with the SARS–CoV–2 virus (*e.g.,* a viral test); (ii) Administered in accordance with the authorized instructions; and (iii) Not both self-administered and self-read unless observed by the employer or an authorized telehealth proctor. Examples of tests that satisfy this requirement include tests with specimens that are processed by a laboratory (including home or on-site collected specimens which are processed either individually or as pooled specimens), proctored over-the-counter tests, point of care tests, and tests where specimen collection and processing is either done or observed by an employer. Employers may have costs associated with doing, observing or proctoring employee testing, if employers choose to do so. However, for economic feasibility purposes, OSHA does not account for these costs in its estimates because they are not required for compliance with the ETS.

Costs Associated with Reasonable Accommodation: Testing, Face Coverings, and Determinations

The ETS does not require the employer to pay for any costs associated with testing; however employer payment for testing may be required by other laws, regulations, or collective bargaining agreements. Thus, while OSHA does not include any costs for reasonable accommodation requests in its main cost analysis in recognition that such costs would result from the application of other laws, OSHA notes that even if employers were to agree to pay for COVID–19 testing as part of a reasonable accommodation or some other reason required by law, such costs would not alter OSHA's findings regarding the economic feasibility of the rule.[48] OSHA reached this conclusion after conducting a separate analysis of reasonable accommodation costs that an employer might assume if they do not represent an undue hardship for the employer. This analysis is available in the docket at OSHA, October 2021d.

OSHA notes that this separate analysis is limited to employees who request accommodation, and accounts for costs of reviewing medical and/or religious accommodation requests, as

[48] OSHA notes that while the testing required under this standard might be an option for employees who request a reasonable accommodation to avoid vaccination, other alternatives such as telework would be more protective to the employee by preventing COVID–19 exposure. These alternatives may also be available at no additional cost to the employer or employee.

well as costs for COVID–19 testing and face coverings that would satisfy the requirements of this ETS. OSHA expects a reasonable accommodation request could lead to a review of the employee's request by a manager and then a conference between the manager and the employee. OSHA concludes that the combination of these costs would not alter OSHA's findings regarding the economic feasibility of the ETS.

f. Employee Notification to Employer of a Positive COVID–19 Test and Removal

ETS Requirements

Under § 1910.501(h):

Regardless of COVID–19 vaccination status or any COVID–19 testing required under paragraph (g) of the ETS, the employer must:

- Require each employee to promptly notify the employer when they receive a positive COVID–19 test or are diagnosed with COVID–19 by a licensed healthcare provider; and
- Immediately remove from the workplace any employee who receives a positive COVID–19 test or is diagnosed with COVID–19 by a licensed healthcare provider and keep the employee removed until the employee: (i) Receives a negative result on a COVID–19 nucleic acid amplification test (NAAT) following a positive result on a COVID–19 antigen test if the employee chooses to seek a NAAT test for confirmatory testing; (ii) meets the return to work criteria in CDC's ''Isolation Guidance'' (incorporated by reference, § 1910.509); or (iii) receives a recommendation to return to work from a licensed healthcare provider.

Costs Analysis Assumptions

The ETS does not require employers to provide paid time off to any employee for removal from the workplace as a result of a positive COVID–19 test or diagnosis of COVID–19; however paid time off may be required by other laws, regulations, or collective bargaining agreements or other collectively negotiated agreements. Therefore, there are no costs associated with paragraph (h)'s removal provision.

With respect to notification, to the extent employee notification is connected to the ETS's testing and documentation requirements in paragraph (g), those costs to the employer are taken under the costs for recordkeeping, discussed below, because, as explained above, receiving documentation of test results under paragraph (g) will be part and parcel of the recordkeeping process.

OSHA notes also that the costs associated with employee notification by vaccinated employees (not required by this ETS to undergo testing) should also be negligible because it will not occur with any real frequency. The very low breakthrough rates of infection among vaccinated persons suggests that the overwhelming majority of COVID–19 cases reported to a covered employer will be in the pool of unvaccinated employees.

g. Reporting COVID–19 Fatalities and Hospitalizations to OSHA

ETS Requirements

Under § 1910.501(j):

The employer must report to OSHA:

- Each work-related COVID–19 fatality within 8 hours of the employer learning about the fatality.
- Each work-related COVID–19 in-patient hospitalization within 24 hours of the employer learning about the in-patient hospitalization.

When reporting COVID–19 fatalities and in-patient hospitalizations to OSHA in accordance with paragraph (j)(1) of the ETS, the employer must follow the requirements in 29 CFR part 1904.39, except for 29 CFR part 1904.39(a)(1) and (2) and (b)(6).

Cost Analysis Assumptions

OSHA estimates a total of 1,464 fatalities and 59,570 hospitalizations for employees of covered firms.[49] This analysis is broadly consistent, using updated data, with OSHA's analysis of a nearly identical provision in 29 CFR 1910.502, the Healthcare ETS. OSHA also estimates, based on the Healthcare ETS, that reporting of each fatality and hospitalization will require 45 minutes of an employer's time (86 FR at 32516). This includes hospitalizations and fatalities for employees that remain unvaccinated, as well as a small percentage of hospitalizations and fatalities of vaccinated employees due to breakthrough cases. Because of the timing requirements in the rule, the agency assumes that a hospitalization followed by a death will need two reports from the employer (*i.e.,* the agency assumes that reporting for hospitalizations will occur within 8 hours, before reporting for fatalities occurs, within 24 hours). This will result in a slight over-estimate.

The total cost for reporting COVID–19 fatalities and hospitalizations to OSHA is calculated as the product of:

- One-time labor burden of 45 minutes per report of hospitalization or fatality.
- Wage range for General and Operations Managers (SOC code 11–1021, NAICS-specific wages).
- Total number of fatalities for employees at covered firms.
- Total number of hospitalizations for employees at covered firms.

Cost for Reporting COVID–19 Fatalities and Hospitalizations to OSHA

Costs per entity and total costs for vaccination are shown below in Table IV.B.11.

[49] These counts represent hospitalizations and fatalities that would occur to the in-scope labor force despite the ETS. The numbers are derived using methodology similar to that used in Health Impacts to generate hospitalizations and fatalities prevented. An infection rate and case fatality rate are multiplied by the number of unvaccinated workers to derive a total number of fatalities. That number is used to derive hospitalizations. The number of hospitalizations and fatalities to vaccinated employees is calculated in a similar fashion, but with a lower infection rate because vaccination makes it considerably less likely that an individual will be tested and found to be infected. See (OSHA, October 2021a and OSHA, October 2021c). One difference in methodology between these counts and the Health Impacts analysis is that these counts use a baseline of the last 19 months of CDC data to estimate the case fatality rate (similar to Alternative C in the Health Impacts analysis), rather than a baseline of the last 6 months (which OSHA used for the main Health Impacts analysis). This results in an estimate toward the upper bound for these counts (*i.e.,* an overestimate of costs).

Table IV.B.11. Reporting COVID-19 Fatalities and Hospitalizations to OSHA

NAICS 3	NAICS Description	Cost per Entity	Total Cost
	All Industry	**$16**	**$4,352,190**
111	Crop Production	$7	$170,598
112	Animal Production and Aquaculture	$7	$189,656
113	Forestry and Logging	$5	$241
114	Fishing, Hunting and Trapping	$5	$40
115	Support Activities for Agriculture and Forestry	$8	$1,978
211	Oil and Gas Extraction	$14	$3,708
213	Support Activities for Mining	$19	$10,375
221	Utilities	$34	$28,342
236	Construction of Buildings	$11	$16,845
237	Heavy and Civil Engineering Construction	$17	$29,589
238	Specialty Trade Contractors	$10	$55,724
311	Food Manufacturing	$25	$66,122
312	Beverage and Tobacco Product Manufacturing	$16	$5,541
313	Textile Mills	$13	$3,721
314	Textile Product Mills	$11	$2,600
315	Apparel Manufacturing	$8	$1,713
316	Leather and Allied Product Manufacturing	$12	$726
321	Wood Product Manufacturing	$11	$11,315
322	Paper Manufacturing	$22	$15,902
323	Printing and Related Support Activities	$10	$8,923
324	Petroleum and Coal Products Manufacturing	$18	$5,418
325	Chemical Manufacturing	$17	$38,630
326	Plastics and Rubber Products Manufacturing	$16	$33,463
327	Nonmetallic Mineral Product Manufacturing	$14	$14,551
331	Primary Metal Manufacturing	$20	$18,094
332	Fabricated Metal Product Manufacturing	$10	$37,618
333	Machinery Manufacturing	$15	$40,284
334	Computer and Electronic Product Manufacturing	$21	$35,431
335	Electrical Equipment, Appliance, and Component Manufacturing	$19	$15,232
336	Transportation Equipment Manufacturing	$40	$77,976
337	Furniture and Related Product Manufacturing	$17	$12,192
339	Miscellaneous Manufacturing	$15	$15,807
423	Merchant Wholesalers, Durable Goods	$8	$75,973
424	Merchant Wholesalers, Nondurable Goods	$10	$57,962
425	Wholesale Electronic Markets and Agents and Brokers	$13	$4,561
441	Motor Vehicle and Parts Dealers	$13	$50,059
442	Furniture and Home Furnishings Stores	$21	$8,596
443	Electronics and Appliance Stores	$31	$7,320
444	Building Material and Garden Equipment and Supplies Dealers	$25	$29,599
445	Food and Beverage Stores	$37	$70,844
446	Health and Personal Care Stores	$36	$23,972
447	Gasoline Stations	$11	$13,995
448	Clothing and Clothing Accessories Stores	$55	$51,222
451	Sporting Goods, Hobby, Musical Instrument, and Book Stores	$37	$10,496
452	General Merchandise Stores	$576	$81,150
453	Miscellaneous Store Retailers	$11	$11,354
454	Nonstore Retailers	$11	$15,609
481	Air Transportation	$84	$23,889
482	Rail Transportation	$1,158	$9,261
483	Water Transportation	$17	$2,615

NAICS 3	NAICS Description	Cost per Entity	Total Cost
484	Truck Transportation	$14	$36,874
485	Transit and Ground Passenger Transportation	$16	$14,828
486	Pipeline Transportation	$16	$2,172
487	Scenic and Sightseeing Transportation	$6	$477
488	Support Activities for Transportation	$12	$17,088
491	Postal Service	$14	$308
492	Couriers and Messengers	$127	$24,809
493	Warehousing and Storage	$15	$38,579
511	Publishing Industries (except Internet)	$25	$36,571
512	Motion Picture and Sound Recording Industries	$24	$9,705
515	Broadcasting (except Internet)	$27	$9,123
517	Telecommunications	$66	$41,891
518	Data Processing, Hosting, and Related Services	$17	$20,702
519	Other Information Services	$27	$11,662
521	Monetary Authorities-Central Bank	$104	$1,249
522	Credit Intermediation and Related Activities	$25	$99,420
523	Securities, Commodity Contracts, and Other Financial Investments and Related Activities	$15	$26,869
524	Insurance Carriers and Related Activities	$30	$69,815
525	Funds, Trusts, and Other Financial Vehicles	$1	$44
531	Real Estate	$7	$25,048
532	Rental and Leasing Services	$13	$13,025
533	Lessors of Nonfinancial Intangible Assets (except Copyrighted Works)	$3	$787
541	Professional, Scientific, and Technical Services	$15	$214,110
551	Management of Companies and Enterprises	$7	$124,714
561	Administrative and Support Services	$29	$383,143
562	Waste Management and Remediation Services	$13	$10,513
611	Educational Services	$27	$407,919
624	Social Assistance	$14	$173,515
711	Performing Arts, Spectator Sports, and Related Industries	$103	$476,929
712	Museums, Historical Sites, and Similar Institutions	$12	$121,414
713	Amusement, Gambling, and Recreation Industries	$6	$63,293
721	Accommodation	$13	$11,382
722	Food Services and Drinking Places	$8	$3,073
811	Repair and Maintenance	$13	$35,392
812	Personal and Laundry Services	$25	$56,676
Sources: OSHA analysis, BLS 2020 OEWS data (BLS, 2021a), BLS Employer Cost of Compensation (BLS, 2021b), CDC Covid Data Tracker (CDC, October 4, 2021a)			

h. Recordkeeping

ETS Requirements

As discussed above, the full costs for the requirements in paragraph (e) of the ETS are taken under the costs for recordkeeping because determining vaccination status, providing acceptable proof of vaccination status, and creating and maintaining a roster of each employee's vaccination status will be part and parcel of the recordkeeping process. Under paragraph (e)(4) of the ETS, the employer must maintain a record of each employee's vaccination status and must preserve acceptable proof of vaccination for each employee who is fully or partially vaccinated. The employer must also maintain a roster of each employee's vaccination status. These records and roster are considered to be employee medical records and must be maintained in accordance with 29 CFR 1910.1020 as such records and must not be disclosed except as required or authorized by the ETS or other federal law. These records and roster are not subject to the retention requirements of 29 CFR 1910.1020(d)(1)(i) but must be maintained and preserved while the ETS remains in effect.

With respect to vaccination, it should be noted that, under paragraph (e)(5) of the ETS, when an employer has ascertained employee vaccination status prior to the effective date of this section through another form of attestation or proof, and retained records of that ascertainment, the employer is exempt from the determination of vaccination requirements in paragraphs (e)(1)–(e)(3)

only for each employee whose fully vaccinated status has been documented prior to the effective date of this section. For purposes of the recordkeeping requirements in paragraph (e)(4), the employer's records of ascertainment of vaccination status for each such person constitute acceptable proof of vaccination. OSHA estimates, based on this provision, that 60% of employees who were vaccinated prior to the promulgation of the ETS will not need to document vaccination status in connection with paragraph (e) (ASU COVID–19 Diagnostic Commons, October 6, 2021).

As also discussed above, the costs for the requirements for documenting test results in paragraph (g), including the timing for when recordkeeping costs for testing accrue under the ETS, are taken under the costs for recordkeeping because providing documentation of test results to the employer will be part and parcel of the recordkeeping process. Under paragraph (g)(4) of the ETS, the employer must maintain a record of each test result provided by each employee under paragraph (g)(1) of the ETS or obtained during tests conducted by the employer. These records must be maintained in accordance with 29 CFR 1910.1020 and must not be disclosed except as required or authorized by this section or other federal law. These records are not subject to the retention requirements of 29 CFR 1910.1020(d)(1)(i) but must be maintained and preserved while this section remains in effect.

With respect to testing, it should be noted that, under paragraph (m) of the ETS, employers are not required to comply with the requirements in paragraph (g) of the ETS until 60 days after the effective date of the ETS, meaning that for cost analysis purposes OSHA assumes that employers would not receive any testing records until the end of that 60-day period.

Finally, under paragraph 1910.501(l)(1) of the ETS, *availability of records,* by the end of the next business day after a request, the employer must make available, for examination and copying, the individual COVID–19 vaccine documentation and any COVID–19 test results for a particular employee to that employee and to anyone having written authorized consent of that employee. In addition, under paragraph 1910.501(l)(2) of the ETS, by the end of the next business day after a request by an employee or an employee representative, the employer must make available to the requester the aggregate number of fully vaccinated employees at a workplace along with the total number of employees at that workplace. Under paragraph 1910.501(l)(3) of the ETS, the employer must also provide to the Assistant Secretary for examination and copying: (i) Within 4 business hours of a request, the employer's written policy required by paragraph (d) of the ETS, and the aggregate numbers described in paragraph (l)(2) of the ETS; and (ii) By the end of the next business day after a request, all other records and other documents required to be maintained by the ETS.

Cost Analysis Assumptions

To fulfill the recordkeeping requirements in the ETS, OSHA estimates that it will take an average of 5 minutes of clerical time per employee record. OSHA bases this cost estimate on the estimate for recordkeeping in the Healthcare ETS (86 FR at 32515). While OSHA estimated an average of 10 minutes of clerical time per employee record in the Healthcare ETS, that standard includes more extensive recordkeeping requirements than what is being required under this ETS. See 29 CFR 1910.502(q)(2)(ii) (Healthcare ETS record must contain, for each instance, the employee's name, one form of contact information, occupation, location where the employee worked, the date of the employee's last day at the workplace, the date of the positive test for, or diagnosis of, COVID–19, and the date the employee first had one or more COVID–19 symptoms, if any were experienced).

In addition, OSHA includes in this estimate 5 minutes of employee time to provide documentation of vaccination status or testing, as applicable, to the employer. OSHA notes that, for an employee who is vaccinated, the employer will determine the vaccination status of that employees and obtain acceptable proof of vaccination status at the same time, thus negating the need to create two separate records for these requirements.

OSHA notes that there will be a cost associated with setting up the recordkeeping system (*e.g.,* a spreadsheet) used to comply with the ETS. OSHA takes these costs in connection with the costs for the employer policy on vaccination, which are described above.

Given the relative complexity of recordkeeping in the Healthcare ETS, OSHA has simplified its assumptions to reflect a variety of small costs in a combined estimate. As in the Healthcare ETS, the cost estimate of 5 minutes per event is likely much higher than necessary to account for just the actions of receiving and maintaining copies of records, so retaining this time will yield a tendency toward overestimation. However, this cost also reflects a margin to encompass additional outlier costs such as a second documentation of vaccination status for all employees who need to submit documentation twice (first for partial vaccination and then for full vaccination) under the ETS. This 5 minutes for recordkeeping also encompasses the marginal time for creating and maintaining a roster of each employee's vaccination status (paragraph (e)) and making aggregate employee data available (paragraph (l)). Since normally the system used for recordkeeping will be electronic in businesses with more than 100 employees, the time to create an aggregate report and a roster should be de minimis. Finally, this inflated recordkeeping cost encompasses time for employee notification to the employer of a positive COVID–19 test connected to the ETS's testing and documentation requirements in paragraph (g),which is a notification under paragraph (h). Finally, the burden of making available, for examination and copying, the individual COVID–19 vaccine documentation and any COVID–19 test results for a particular employee are included in this estimate because this documentation will normally be pulled from the electronic recordkeeping system described above.[50]

[50] The cost of providing to the Assistant Secretary for examination and copying the employer's written policy required by paragraph (d) of the ETS will be de minimis.

The total cost for these requirements is calculated based on:

- One-time labor burden of 5 minutes of employee labor to provide documentation and 5 minutes of clerk labor per employee record (one record per test administered and one record per documentation of vaccination status).
- The average labor rate for Office Clerks, General (SOC 43–9060, NAICS-specific wages) and employees providing documentation (average wage over all employees, NAICS-specific wages)
- Total number of employees at covered firms getting vaccinated due to the ETS with the Johnson & Johnson vaccine, who receive one shot.
- Total number of employees at covered firms getting vaccinated due to the ETS with the Pfizer-BioNTech and Moderna vaccines, multiplied by two to account for two shots.
- Total number of tests for employees at covered firms who are unvaccinated and will get vaccinated by receiving the Johnson and Johnson vaccine.
- Total number of tests for employees at covered firms who are unvaccinated and will get vaccinated by receiving the Pfizer and Moderna vaccines.
- Total number of employees at covered firms who are unvaccinated and will be tested weekly.

Cost for Recordkeeping

Costs per entity and total costs for recordkeeping are shown below in Table IV.B.12.

Table IV.B.12. Recordkeeping

NAICS 3	NAICS Description	Recordkeeping Cost (for test results)		Recordkeeping Cost (for vaccination status)	
		Cost per Entity	Total Cost	Cost per Entity	Total Cost
	All Industries	**$2,287**	**$603,531,029**	**$1,187**	**$313,198,683**
111	Crop Production	$1,010	$23,952,624	$529	$12,551,553
112	Animal Production and Aquaculture	$1,010	$26,628,530	$529	$13,953,770
113	Forestry and Logging	$637	$33,784	$334	$17,710
114	Fishing, Hunting and Trapping	$698	$5,580	$366	$2,924
115	Support Activities for Agriculture and Forestry	$959	$245,521	$503	$128,693
211	Oil and Gas Extraction	$2,327	$602,692	$1,220	$315,925
213	Support Activities for Mining	$2,588	$1,417,970	$1,357	$743,429
221	Utilities	$5,746	$4,837,466	$3,012	$2,535,854
236	Construction of Buildings	$1,615	$2,522,966	$847	$1,322,291
237	Heavy and Civil Engineering Construction	$2,464	$4,170,744	$1,292	$2,186,839
238	Specialty Trade Contractors	$1,535	$8,386,705	$805	$4,397,204
311	Food Manufacturing	$2,768	$7,333,205	$1,449	$3,838,594
312	Beverage and Tobacco Product Manufacturing	$2,359	$799,570	$1,235	$418,777
313	Textile Mills	$1,398	$406,763	$733	$213,207
314	Textile Product Mills	$1,360	$329,175	$713	$172,556
315	Apparel Manufacturing	$1,048	$226,355	$549	$118,656
316	Leather and Allied Product Manufacturing	$1,330	$79,809	$696	$41,767
321	Wood Product Manufacturing	$1,374	$1,425,211	$720	$747,070
322	Paper Manufacturing	$2,724	$1,939,691	$1,428	$1,016,731
323	Printing and Related Support Activities	$1,377	$1,179,867	$722	$618,513
324	Petroleum and Coal Products Manufacturing	$2,658	$784,148	$1,393	$410,822
325	Chemical Manufacturing	$2,270	$5,018,016	$1,185	$2,619,510
326	Plastics and Rubber Products Manufacturing	$1,868	$3,835,982	$979	$2,010,681
327	Nonmetallic Mineral Product Manufacturing	$1,790	$1,870,975	$937	$979,657
331	Primary Metal Manufacturing	$2,336	$2,139,736	$1,224	$1,121,454
332	Fabricated Metal Product Manufacturing	$1,220	$4,699,701	$639	$2,463,179
333	Machinery Manufacturing	$1,842	$5,023,299	$966	$2,633,020
334	Computer and Electronic Product Manufacturing	$2,822	$4,814,766	$1,479	$2,523,189
335	Electrical Equipment, Appliance, and Component Manufacturing	$2,175	$1,746,513	$1,140	$915,547
336	Transportation Equipment Manufacturing	$5,091	$9,942,644	$2,669	$5,212,394
337	Furniture and Related Product Manufacturing	$1,884	$1,354,943	$988	$710,051
339	Miscellaneous Manufacturing	$1,846	$1,982,223	$966	$1,038,013
423	Merchant Wholesalers, Durable Goods	$1,232	$11,076,712	$646	$5,804,380
424	Merchant Wholesalers, Nondurable Goods	$1,325	$7,512,074	$695	$3,937,217
425	Wholesale Electronic Markets and Agents and Brokers	$1,965	$672,177	$1,030	$352,254
441	Motor Vehicle and Parts Dealers	$1,625	$6,217,834	$852	$3,259,252
442	Furniture and Home Furnishings Stores	$3,176	$1,318,080	$1,665	$690,774
443	Electronics and Appliance Stores	$4,621	$1,104,393	$2,423	$579,107
444	Building Material and Garden Equipment and Supplies Dealers	$3,690	$4,398,232	$1,934	$2,305,607

NAICS 3	NAICS Description	Recordkeeping Cost (for test results)		Recordkeeping Cost (for vaccination status)	
		Cost per Entity	Total Cost	Cost per Entity	Total Cost
445	Food and Beverage Stores	$6,014	$11,589,923	$3,154	$6,076,966
446	Health and Personal Care Stores	$6,397	$4,240,986	$3,224	$2,137,542
447	Gasoline Stations	$1,794	$2,390,209	$940	$1,252,737
448	Clothing and Clothing Accessories Stores	$7,832	$7,236,459	$4,106	$3,794,360
451	Sporting Goods, Hobby, Musical Instrument, and Book Stores	$5,607	$1,575,462	$2,939	$825,970
452	General Merchandise Stores	$82,519	$11,635,150	$43,232	$6,095,648
453	Miscellaneous Store Retailers	$1,589	$1,603,180	$833	$840,020
454	Nonstore Retailers	$1,454	$2,103,588	$759	$1,098,429
481	Air Transportation	$14,328	$4,069,189	$7,513	$2,133,682
482	Rail Transportation	$180,125	$1,440,996	$94,425	$755,399
483	Water Transportation	$2,292	$362,197	$1,202	$189,872
484	Truck Transportation	$2,178	$5,657,452	$1,142	$2,964,963
485	Transit and Ground Passenger Transportation	$2,187	$2,027,722	$1,147	$1,062,867
486	Pipeline Transportation	$2,955	$393,080	$1,550	$206,103
487	Scenic and Sightseeing Transportation	$896	$72,585	$469	$38,020
488	Support Activities for Transportation	$1,777	$2,537,777	$931	$1,329,808
491	Postal Service	$2,133	$47,963	$1,119	$25,150
492	Couriers and Messengers	$19,783	$3,857,615	$10,373	$2,022,803
493	Warehousing and Storage	$1,911	$4,941,215	$1,002	$2,589,550
511	Publishing Industries (except Internet)	$4,243	$6,267,417	$2,225	$3,286,111
512	Motion Picture and Sound Recording Industries	$3,511	$1,425,477	$1,838	$746,053
515	Broadcasting (except Internet)	$3,917	$1,316,232	$2,054	$690,064
517	Telecommunications	$10,085	$6,424,104	$5,286	$3,367,055
518	Data Processing, Hosting, and Related Services	$2,585	$3,110,309	$1,356	$1,630,732
519	Other Information Services	$4,234	$1,824,667	$2,218	$955,901
521	Monetary Authorities-Central Bank	$14,505	$174,061	$7,606	$91,271
522	Credit Intermediation and Related Activities	$3,554	$14,037,835	$1,863	$7,359,466
523	Securities, Commodity Contracts, and Other Financial Investments and Related Activities	$2,127	$3,745,639	$1,113	$1,960,350
524	Insurance Carriers and Related Activities	$3,946	$9,206,638	$2,059	$4,804,542
525	Funds, Trusts, and Other Financial Vehicles	$213	$6,826	$112	$3,571
531	Real Estate	$1,021	$3,694,899	$535	$1,935,836
532	Rental and Leasing Services	$1,917	$1,879,116	$1,005	$984,414
533	Lessors of Nonfinancial Intangible Assets (except Copyrighted Works)	$502	$120,581	$263	$63,199
541	Professional, Scientific, and Technical Services	$2,211	$32,018,996	$1,154	$16,712,840
551	Management of Companies and Enterprises	$1,060	$18,536,501	$554	$9,690,931
561	Administrative and Support Services	$3,554	$46,688,782	$1,847	$24,263,635
562	Waste Management and Remediation Services	$1,888	$1,549,394	$989	$811,756
611	Educational Services	$3,826	$58,254,126	$1,995	$30,381,942
624	Social Assistance	$2,111	$26,577,503	$1,066	$13,427,085

NAICS 3	NAICS Description	Recordkeeping Cost (for test results)		Recordkeeping Cost (for vaccination status)	
		Cost per Entity	Total Cost	Cost per Entity	Total Cost
711	Performing Arts, Spectator Sports, and Related Industries	$13,337	$61,863,380	$6,634	$30,769,875
712	Museums, Historical Sites, and Similar Institutions	$1,611	$16,030,837	$823	$8,193,657
713	Amusement, Gambling, and Recreation Industries	$861	$8,935,270	$450	$4,671,160
721	Accommodation	$1,884	$1,626,234	$985	$850,192
722	Food Services and Drinking Places	$1,116	$434,162	$583	$226,973
811	Repair and Maintenance	$1,784	$4,893,622	$931	$2,554,214
812	Personal and Laundry Services	$3,165	$7,318,444	$1,615	$3,733,079
813	Religious, Grantmaking, Civic, Professional, and Similar Organizations	$2,452	$28,414,270	$1,282	$14,852,626

i. Summary of Total Cost

Total Cost and Total Cost per Entity

Table IV.B.13. Total Costs

NAICS 3	NAICS Description	Cost per Entity	Total Cost
	All	**$11,298**	**$2,981,347,368**
111	Crop Production	$5,442	$129,049,269
112	Animal Production and Aquaculture	$5,442	$143,466,214
113	Forestry and Logging	$3,520	$186,556
114	Fishing, Hunting and Trapping	$3,909	$31,272
115	Support Activities for Agriculture and Forestry	$4,482	$1,147,268
211	Oil and Gas Extraction	$13,058	$3,382,027
213	Support Activities for Mining	$13,032	$7,141,522
221	Utilities	$29,281	$24,649,875
236	Construction of Buildings	$8,559	$13,368,408
237	Heavy and Civil Engineering Construction	$12,466	$21,104,850
238	Specialty Trade Contractors	$7,982	$43,622,949
311	Food Manufacturing	$12,840	$34,013,981
312	Beverage and Tobacco Product Manufacturing	$11,509	$3,901,548
313	Textile Mills	$6,875	$2,000,719
314	Textile Product Mills	$6,545	$1,583,885
315	Apparel Manufacturing	$5,226	$1,128,808
316	Leather and Allied Product Manufacturing	$6,596	$395,762
321	Wood Product Manufacturing	$6,680	$6,927,322
322	Paper Manufacturing	$13,434	$9,564,937
323	Printing and Related Support Activities	$6,946	$5,952,466
324	Petroleum and Coal Products Manufacturing	$14,194	$4,187,128
325	Chemical Manufacturing	$12,119	$26,795,553
326	Plastics and Rubber Products Manufacturing	$9,097	$18,684,432
327	Nonmetallic Mineral Product Manufacturing	$9,368	$9,789,836
331	Primary Metal Manufacturing	$11,459	$10,496,406
332	Fabricated Metal Product Manufacturing	$6,204	$23,899,213
333	Machinery Manufacturing	$9,680	$26,396,316
334	Computer and Electronic Product Manufacturing	$15,166	$25,873,149
335	Electrical Equipment, Appliance, and Component Manufacturing	$10,986	$8,822,008
336	Transportation Equipment Manufacturing	$24,960	$48,746,936
337	Furniture and Related Product Manufacturing	$8,764	$6,301,346
339	Miscellaneous Manufacturing	$9,516	$10,220,706
423	Merchant Wholesalers, Durable Goods	$6,697	$60,195,312
424	Merchant Wholesalers, Nondurable Goods	$6,938	$39,332,705
425	Wholesale Electronic Markets and Agents and Brokers	$10,702	$3,660,154
441	Motor Vehicle and Parts Dealers	$8,245	$31,546,370
442	Furniture and Home Furnishings Stores	$14,542	$6,034,911
443	Electronics and Appliance Stores	$21,381	$5,110,108
444	Building Material and Garden Equipment and Supplies Dealers	$16,569	$19,749,811
445	Food and Beverage Stores	$25,463	$49,067,290
446	Health and Personal Care Stores	$27,855	$18,467,936
447	Gasoline Stations	$7,582	$10,099,493
448	Clothing and Clothing Accessories Stores	$33,708	$31,146,437
451	Sporting Goods, Hobby, Musical Instrument, and Book Stores	$24,081	$6,766,742
452	General Merchandise Stores	$363,714	$51,283,645
453	Miscellaneous Store Retailers	$7,559	$7,626,924
454	Nonstore Retailers	$7,718	$11,168,383
481	Air Transportation	$73,790	$20,956,234
482	Rail Transportation	$894,389	$7,155,113
483	Water Transportation	$11,616	$1,835,325

NAICS 3	NAICS Description	Cost per Entity	Total Cost
484	Truck Transportation	$10,865	$28,215,195
485	Transit and Ground Passenger Transportation	$10,077	$9,341,127
486	Pipeline Transportation	$14,968	$1,990,734
487	Scenic and Sightseeing Transportation	$4,479	$362,761
488	Support Activities for Transportation	$8,908	$12,721,011
491	Postal Service	$9,547	$214,648
492	Couriers and Messengers	$86,970	$16,959,204
493	Warehousing and Storage	$8,777	$22,689,579
511	Publishing Industries (except Internet)	$23,455	$34,643,707
512	Motion Picture and Sound Recording Industries	$18,692	$7,588,937
515	Broadcasting (except Internet)	$21,006	$7,058,001
517	Telecommunications	$54,096	$34,459,044
518	Data Processing, Hosting, and Related Services	$14,815	$17,822,789
519	Other Information Services	$23,212	$10,004,362
521	Monetary Authorities-Central Bank	$74,846	$898,148
522	Credit Intermediation and Related Activities	$18,755	$74,083,278
523	Securities, Commodity Contracts, and Other Financial Investments and Related Activities	$11,696	$20,597,425
524	Insurance Carriers and Related Activities	$20,558	$47,962,719
525	Funds, Trusts, and Other Financial Vehicles	$1,924	$61,571
531	Real Estate	$5,739	$20,769,860
532	Rental and Leasing Services	$9,762	$9,566,822
533	Lessors of Nonfinancial Intangible Assets (except Copyrighted Works)	$3,347	$803,350
541	Professional, Scientific, and Technical Services	$12,407	$179,657,518
551	Management of Companies and Enterprises	$6,321	$110,569,142
561	Administrative and Support Services	$16,438	$215,961,913
562	Waste Management and Remediation Services	$9,419	$7,727,913
611	Educational Services	$19,897	$302,982,220
624	Social Assistance	$10,078	$126,878,714
711	Performing Arts, Spectator Sports, and Related Industries	$58,393	$270,849,435
712	Museums, Historical Sites, and Similar Institutions	$7,173	$71,394,264
713	Amusement, Gambling, and Recreation Industries	$4,181	$43,366,540
721	Accommodation	$9,537	$8,230,144
722	Food Services and Drinking Places	$5,816	$2,262,332
811	Repair and Maintenance	$8,266	$22,675,008
812	Personal and Laundry Services	$13,094	$30,274,382
813	Religious, Grantmaking, Civic, Professional, and Similar Organizations	$10,199	$118,160,993
Sources: OSHA analysis			

j. Sensitivity Analysis

As stated above, based on limited data on current vaccine mandate implementation and forecasts for future implementation (Mishra and Hartstein, August 23, 2021; ASU COVID–19 Diagnostic Commons, October 6, 2021), OSHA estimates that 25 percent of firms in scope currently have a vaccination mandate, and assumes that this will rise to 60 percent of covered employers after the ETS is in place. Because the agency has no historic reference on which to base its assumptions regarding vaccine mandates, the agency adjusted the percentage of firms that will institute a vaccine mandate because of the ETS as part of a sensitivity analysis. Along with

the baseline estimate of 60 percent of firms having a mandate, the agency looked at a vaccine mandate rate of 40 percent and 80 percent for covered firms, which OSHA judged to be a reasonable range based on the data available. The total costs associated with a 40 percent vaccine mandate are $2.998 billion, and the total costs associated with an 80 percent vaccine mandate are $2.964 billion. This compares to the baseline costs associated with a 60 percent vaccine mandate of $2.981 billion. A higher vaccine mandate increases the share of employees who get vaccinated while reducing the share that must get weekly testing. It is this shift in shares that causes the costs to change because the total costs associated with weekly testing (recordkeeping) are more expensive than the total costs associated with vaccination under the ETS (employer support for vaccination, recordkeeping).

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V. ETS Economic Feasibility Determination

a. OSHA's Screening Tests for Economic Feasibility

As noted in the introduction to the economic analysis, an OSHA standard is economically feasible when industries can absorb or pass on the costs of compliance without threatening industry's long-term profitability or competitive structure, *Cotton Dust*, 452 U.S. at 530 n.55, or ''threaten[ing] massive dislocation to, or imperil[ing] the existence of, the industry.'' *United Steelworkers of Am.* v. *Marshall (Lead I),* 647 F.2d 1189, 1272 (D.C. Cir. 1981).

To determine whether a rule is economically feasible, OSHA typically begins by using two screening tests to determine whether the costs of the rule are beneath the threshold level at which the economic feasibility of an affected industry might be threatened. The first screening test is a revenue test. While there is no hard and fast rule on which to base the threshold, OSHA generally considers a standard to be economically feasible for an affected industry when the annualized costs of compliance are less than one percent of annual revenues. The one-percent revenue threshold is intentionally set at a low level so that OSHA can confidently assert that the rule is economically feasible for industries that are below the threshold (*i.e.,* industries for which the costs of compliance are less than one percent of annual revenues). To put the one-percent threshold into perspective, OSHA calculated the average compounded annual rate of growth or decay in average revenues over the 15-year period from 2002 to 2017 (inflated to 2005 to 2020 dollars) for firms with 100 or more employees in the 479 NAICS (out of 546) industries covered by this ETS for which Census data were available and found that the average annual real rate of change in revenues in absolute terms for the average firm was 2.2 percentage points a year.[51] In other words, revenues are generally observed to change by well more than one percent per year, on average, for firms with 100 or more employees in covered industries, indicating that changes of this magnitude are normal in these industries and that covered firms are typically able to withstand such changes over the course of a year, much less six months. As discussed below, the average percentage change due to this ETS for all covered NAICS is a fraction of this fluctuation in revenues.

The second screening test that OSHA traditionally uses to consider whether a standard is economically feasible for an affected industry is if the costs of compliance are less than ten percent of annual profits (see, *e.g.,* OSHA's economic analysis of its Silica standard, 81 FR 16286, 16533 (March 25, 2016); upheld in *N. Am.'s Bldg. Trades Unions* v. *OSHA,* 878 F.3d 271, 300 (D.C. Cir. 2017)). The ten-percent profit test is also intended to be at a sufficiently low level so as to allow OSHA to identify industries that might require further examination. Specifically, the profit screen is primarily used to alert OSHA to potential impacts on industries where the price elasticity of demand does not allow for ready absorption of new costs in higher prices (*e.g.,* industries with foreign competition where the American firms would incur costs that their foreign competitors would not because they are not subject to OSHA requirements). In addition, setting the threshold for the profit test low permits OSHA to reasonably conclude that the rule would be economically feasible for industries below the threshold. To put the ten-percent profit threshold test into perspective, evidence used by OSHA in its 2016 OSHA silica rule indicates that, for the combined affected manufacturing industries in general industry and maritime from 2000 through 2012, the average year-to-year fluctuation in profit rates (both up and

[51] These results are presented in the Excel ETS Revenue Threshold Test Tables available in the Docket for this ETS. The data used for six-digit NAICS were from the Bureau of the Census, available every five years (2002, 2007, 2012, 2107).

down) was 138.5 percent (81 FR 16545).[52]

When an industry ''passes'' both the ''cost-to-revenue'' and ''cost-to-profit'' screening tests, OSHA is assured that the costs of compliance with the rule are economically feasible for that industry. The vast majority of the industries covered by the ETS fall into this category.

A rule is not necessarily economically infeasible, however, for the industries that do not pass the initial revenue screening test (*i.e.,* those for which the costs of compliance with the rule are one percent or more of annual revenues), the initial profit screening test (*i.e,* those for which the costs of compliance are ten percent or more of annual profits), or both. Instead, OSHA normally views those industries as requiring additional examination as to whether the rule would be economically feasible (see *N. Am.'s Bldg. Trades Unions* v. *OSHA,* 878 F.3d at 291). OSHA therefore conducts further analysis of the industries that ''fail'' one or both of the screening tests in order to evaluate whether the rule would threaten the existence or competitive structure of those industries (see *United Steelworkers of Am., AFL–CIO–CLC* v. *Marshall,* 647 F.2d 1189, 1272 (D.C. Cir. 1980)).

Time Parameters for Analysis

OSHA's economic analyses almost always measure the costs of a standard on an annual basis, conducting the screening tests by measuring the cost of the standard against the annual profits and annual revenues for a given industry. One year is typically the minimum period for evaluating the status of a business; for example, most business filings for tax or financial purposes are annual in nature.

Some compliance costs are up-front costs and others are spread over the duration of the ETS; regardless, the costs of the rule overall will not typically be incurred or absorbed by businesses all at once. However, OSHA does not expect that the ETS will require employers to incur initial capital costs for equipment to be used over many years (which would typically be addressed through installments over a year or a longer period to leverage loans or payment options to allow more time to marshal revenue and minimize impacts on reserves).

The compliance costs for this ETS are for a temporary rule for a period of six months (which, again, is the time period that OSHA assumes this ETS will last, solely for economic purposes). While OSHA believes the most appropriate screens would be based on annual profits and revenue, it has followed the more cautious route of basing the screens on 6 months of profits and revenues to avoid any potential uncertainty about whether the ETS is economically feasible for the industries covered by this ETS. Using one year of revenues and profits as the denominators in the cost-to-revenue and cost-to-profit ratios would have resulted in ratios that are half of the estimated ratios presented in this analysis. It is therefore unsurprising that businesses in some number of NAICs have edged above the profit-thresholds using a 6 month screen (as will be discussed later), and OSHA believes that edging above the screening thresholds is less of an indicator of economic peril in this context than in the context of a permanent rulemaking analysis. Nevertheless, OSHA has examined each of the NAICS that did not clear either of these conservative screening tests and has concluded that the ETS is economically feasible for each one.

Data Used for the Screening Tests

The estimated costs of complying with the ETS, which OSHA relied upon to examine feasibility is based on the two tests described above (see OSHA, October 2021a). The revenue numbers used to determine cost-to-revenue ratios were obtained from the 2017 Economic Census for firms with 100 or more employees in covered industries. This is the most current information available from this source, which OSHA considers to be the best available source of revenue data for U.S. businesses.[53] OSHA adjusted these figures to 2020 dollars using the Bureau of Economic Analysis's GDP deflator, which is OSHA's standard source for inflation and deflation analysis.

The profit screening test for feasibility (*i.e.,* the cost-to-profit ratio) was calculated as ETS costs divided by profits. Profits were calculated as profit rates multiplied by revenues. The before-tax profit rates that OSHA used were estimated using corporate balance sheet data from the Internal Revenue Service (IRS), 2013 *Corporation Source Book* (IRS, 2013). The IRS discontinued the publication of these data after 2013, and therefore the most current years available are 2000–2013.[54] The most recent version of the Source Book represents the best available evidence for these data on profit rates.[55]

For each of the years 2000 through 2013, OSHA calculated profit rates by dividing the ''net income'' from all firms (both profitable and unprofitable) by total receipts from all firms (both profitable and unprofitable) for each NAICS.[56] OSHA then averaged these rates across the 14-year (2000 through 2013) period. Since some data provided by the IRS were not available at disaggregated levels for all industries and profit rates, data at more highly aggregated levels were used for some industries; that is, where data were not available for each six-digit NAICS code, data for the corresponding four- or five-digit NAICS codes were used. Data were used for all firms in the NAICS (as opposed to just firms with 100 or more employees) since data disaggregated by employment size-class were not available. Profit rates are expressed as a percentage (see OSHA, October 2021a). Profits themselves were used to calculate the cost-to-profit estimates for all firms contained in a particular NAICS code (see OSHA, October 2021a).

OSHA has estimated costs over a 6-month timeframe for this ETS. As discussed above, OSHA has therefore used six months of revenue to conduct the cost-to-revenue tests and six months of profit to conduct the cost-to-profit tests.

General Use of Revenues and Profits To Measure Economic Feasibility

As with other OSHA rulemaking efforts, the agency relies on the two screening tests (costs less than one percent of revenue and costs less than ten percent of profit) as an initial indicator of economic feasibility. OSHA has generally found that the cost-to-revenue test is a more reliable indicator of feasibility simply because the revenue data are more accurate than the profit data. There are several reasons for this.

First, OSHA has been using corporate balance sheet data from the IRS as the best available evidence for estimating

[52] Profits are subject to the dynamics of the overall economy. Many factors, including a national or global recession, a downturn in a particular industry, foreign competition, or the increased competitiveness of producers of close domestic substitutes are all easily capable of causing a decline in profit rates in an industry of well in excess of ten percent in one year or for several years in succession (See OSHA, March 24, 2016).

[53] For information regarding the standards and practices used by the Census Bureau to ensure the quality and integrity of its data, see (US Census Bureau, October 8, 2021a; US Census Bureau, October 8, 2021b).

[54] See IRS, 2013.

[55] OSHA also investigated Bizminer and RMA as potential sources of profit information and determined that they do not represent adequate and random samples of the affected industries.

[56] There is one code reported per tax entity and it may not be representative to the six-digit level. See Corporation Sourcebook on limitations of the industry classification for details. (IRS, 2013).

corporate profits for years.[57] Nevertheless, because firms typically have an incentive to minimize their tax burden, it is reasonable to expect that some of the reported accounting data may have been strategically adjusted to reduce reported profits and their associated tax implications. Business profits are much more likely to reflect such strategic accounting than business revenues; accordingly, revenues are a more accurate measure than profits for evaluating economic feasibility for a multitude of reasons.[58]

Second, because OSHA is using data from both profitable and unprofitable firms, the average profit rate for a small number of industries is negative (as described above, using 14 years of data that predate the pandemic). This result could have occurred because of the way profits are calculated, which unnaturally skews average profit rates downward by including firms that have large losses (negative profits) or subnormal profits and have already closed or are in the process of closing, irrespective of any action by OSHA. The negative rates could also be the result of macroeconomic fluctuations during the 14-year period used to determine the average, a period in which some of these industries may have experienced unusually adverse financial impacts (see, *e.g.,* the explanation in Chapter VI, pp. VI–20 of the Final Economic and Regulatory Flexibility Analysis for OSHA's Rule on Occupational Exposure to Respirable Crystalline Silica, Docket No. OSHA–2010–0034–4247, which notes the skew from negative impacts during recession years (OSHA, March 24, 2016)). Or they could result from tax-related incentives, as previously noted.

Whatever the reason, the cost-to-profit calculations for NAICS with negative profit rates fail to provide reliable information about the long-term profitability of these industries, independent of the ETS. Companies and industries that consistently lose money do not typically stay in business, and would almost certainly not still be in business in 2021 if that loss continued at the same level for each of the 8 years since the profit data was published in 2012. Revenue streams are a more dependable measure for those firms because those streams tend to be more stable and more indicative of the actual capabilities of sustainable firms than reported negative profit margins. As a result, for the purposes of this analysis, OSHA has relied more heavily on its cost-to-revenue estimates, in lieu of cost-to-profit estimates, as the more reliable indicator for economic feasibility for the industries with negative profit rates.

Third, and similarly, profit rates that are only slightly positive (*i.e.,* less than one percent) are inconclusive and not useful for the purpose of OSHA's cost-to-profit test. In economics terms, profit entails a reasonable rate of return on investment, and long-term profits of less than one percent a year are not generally reasonable for firms that expect to remain in business. Thus data showing industry-wide profits in this range do not measure the true ability of companies to pay for the ETS costs. As previously stated, revenue streams tend to be more stable and more indicative of the actual capabilities of sustainable firms. Therefore, where possible, OSHA prefers to rely on the cost-to-revenue test to evaluate economic feasibility for industries that have a less than one percent profit rate.

The qualification, and by far the most important reason for the general primacy of revenues versus profits as the appropriate metric for determining economic feasibility, for most OSHA rules, is that the regulated firms are able to pass on the costs of the rule in the form of higher prices. When they cannot, the profit test functions primarily as a screen for a limited purpose: Alerting OSHA to potential impacts where unregulated competitors can prevent firms from passing costs along to customers.

To understand this point, some economic background is needed. The price elasticity of demand refers to the relationship between the price charged for a product or service and the quantity demanded for that product or service: The more elastic the relationship, the larger the decrease in the quantity demanded for a product when the price goes up. When demand is elastic, establishments have less ability to pass compliance costs on to customers in the form of a price increase and must absorb such costs in the form of reduced profits. In contrast, when demand is relatively inelastic, the quantity demanded for the product or service will be less affected by a change in price. In such cases, establishments can recover most of the variable costs of compliance (*i.e.,* costs that are highly correlated with the amount of output) by raising the prices they charge; under this scenario, if costs are variable rather than fixed, business activity and profit rates are largely unchanged for small changes in costs. Ultimately, where demand is relatively inelastic, any impacts are primarily borne by those customers who purchase the relevant product or service for a slightly higher price. Most of the costs of this ETS are variable costs because they depend primarily on the level of production or the number of employees at an establishment. For example, under the ETS, a firm with 500 employees must determine and record the vaccination status of 500 employees, while a firm with 250 employees need determine and record the vaccination status of only 250 employees.[59]

In general, ''[w]hen an industry is subjected to a higher cost, it does not simply swallow it; it raises its price and reduces its output, and in this way shifts a part of the cost to its consumers and a part to its suppliers'' (*Am. Dental Ass'n v. Sec'y of Labor,* 984 F.2d 823, 829 (7th Cir. 1993)). A reduction in output could happen in a variety of ways: Individual establishments could reduce their levels of service (*e.g.,* retail firms) or production (*e.g.,* manufacturing), both of which could take the form of a reduction of worker hours; some marginal establishments could close; or, in the case of an industry with high turnover of establishments, new entry could be delayed until demand equals supply. In many cases, a decrease in overall output for an industry will be a combination of all three kinds of reductions. The primary means of achieving the reduction in output most likely depends on the rate of turnover in the industry and on the form that the costs of the regulation take. Further, the temporary nature of the ETS and its associated

[57] OSHA funded and accepted a final report by Contractor Henry Beale (Beale Report, 2003) that reviewed alternative financial data sources and concluded that the IRS data were the best. Since then OSHA has been relying on IRS data to provide the financial data to support its rulemaking analyses. See, for example, Occupational Safety and Health Administration (OSHA) (2016), Final Economic and Regulatory Flexibility Analysis for OSHA's Rule on Occupational Exposure to Respirable Crystalline Silica, Chapter VI, pp. VI–2 to VI–3, Docket No. OSHA–2010–0034–4247 (OSHA, March 24, 2016), which includes a more recent review of data sources for corporate financial profit data and further support for OSHA's choice of IRS data.

[58] In fact, all other Department of Labor agencies rely solely on revenues to assess economic impacts, such as Regulatory Flexibility Act certifications, in their rulemakings (see, *e.g.,* Employment and Training Administration, Final Rule on Strengthening Wage Protections for the Temporary and Permanent Employment of Certain Aliens in the United States, *https://www.govinfo.gov/content/pkg/FR-2021-01-14/pdf/2021-00218.pdf;* Wage and Hour Division, Tip Regulations Under the Fair Labor Standards Act (FLSA), *https://www.govinfo.gov/content/pkg/FR-2020-12-30/pdf/2020-28555.pdf*).

[59] While fixed cost can be more limiting in terms of options for businesses, most of the costs of this rule are not fixed. Instead, most of the compliance costs vary with the level of output or employment at a facility.

costs suggests that firms may have more flexibility to respond than when facing a permanent increase in costs. For example, firms may be able to temporarily increase prices or temporarily defer planned capital expenditures or other maintenance to cover compliance costs.

There are two situations typically mentioned when an industry subject to regulatory costs might be unable to pass those costs on: (1) Foreign competition not subject to the regulation, or (2) domestic competitors in other industries, not subject to the regulation, that produce goods or services that are close substitutes. Otherwise, when all affected domestic industries are covered by a rule and foreign businesses must also comply with the rule or are unable to compete effectively, the ability of a competing industry to offer a substitute product or service at a lower price is greatly diminished.

There is a third situation that is relevant to this ETS—when only some firms in a domestic industry (in this case, only employers with 100 or more employees) are subject to the ETS and its regulatory costs. In principle, competition from smaller employers in a NAICS could prevent the larger employers from passing on their costs in the form of higher prices and instead require them to absorb the costs in the form of lost profits. There are, however, several important caveats:

1. As a practical matter, it is implausible to expect that covered employers (with 100 or more employees) would feel constrained by smaller competitors in their industry so as not to pass on costs for a rule lasting 6 months that imposes costs equal to 0.02 percent of revenues, on average across all NAICS, over that time period (see OSHA, October 2021a). This time period would likely be too short for small firms to expand to take business away from the larger firms or for new firms to form to take advantage of such minor and transitory business opportunities. Furthermore, smaller firms (particularly very small firms—those with fewer than 20 employees) typically can't compete on price with large firms that have cost advantages due to various economies of scale; as a result, smaller firms often serve a specialized niche market rather than compete directly with larger firms. To the extent that this ETS creates new business opportunities for these smaller uncovered firms, they would also be covered by the ETS as soon as they reached 100 employees.[60]

2. An important factor to consider in calculating the costs and impacts and economic feasibility of this ETS is the unquantified and unmonetized cost savings and other positive economic impacts accruing to employers that comply with the ETS. These include reduced absenteeism due to COVID–19 illnesses[61] and quarantine.[62] Other positive economic impacts that compliant employers would enjoy from a safer business environment are increased retail trade from customers that feel less at risk and better relations with suppliers and other business partners. These all would contribute to improved business and increased profits.

3. The existence of these cost savings and other positive economic impacts accruing to employers that comply with the ETS suggests that the actual net costs of the ETS will be much lower than the costs reported in the supporting economic analysis for this ETS used to estimate cost impacts and demonstrate economic feasibility. In fact, for some share of covered employers, the net costs of the ETS may well be negative. Indeed, this is being confirmed by revealed preference in the market. Elsewhere in the economic analysis for this ETS (Cost Analysis section 4.2), OSHA has provided evidence to support its estimate that 25 percent of covered employers already voluntarily require that their employees be vaccinated and a much larger percentage are considering a vaccine mandate. This strongly supports the conclusion that these businesses agree that doing so will ultimately save costs.

b. Economic Feasibility Analysis and Determination

This section summarizes OSHA's feasibility findings for industries covered by the ETS. As stated previously, the agency uses two screening tests (costs less than one percent of revenue and costs less than ten percent of profit) as an initial indicator of economic feasibility. In this section, OSHA discusses the industries that fall above the threshold level for either screening test.

The overall effect of compliance with the general section of the ETS on covered industries is very small (see OSHA, October 2021a). The vast majority of the covered NAICS have very low cost-to-revenue and cost-to-profit ratios, with the overall averages being 0.02 percent of revenues and 0.49 percent of profits. To put this into perspective, if the average firm decided to raise prices to cover the costs of the ETS, the price of a $100 product or service, for example, would have to be increased by 2 cents (during the six-month period).

Based on the information presented here, the costs of the ETS are below both the threshold revenue test (1 percent of revenues) and the threshold profit test (10 percent of profits) for the vast majority of NAICS industries.[63] This indicates that the average firm in these industries will be able either to raise prices to cover ETS costs or to absorb the costs of the ETS out of available profits. In either case, OSHA concludes that the ETS is economically feasible for all of these industries.

Critically, there are no industries covered by the general section of the ETS that are above OSHA's cost-to-revenue threshold level of one percent and most are a small fraction of this level. Because OSHA is using data from both profitable and unprofitable firms, the average profit rate for a small number of industries is negative. There are 14 NAICS with negative cost-to-profit ratios, resulting from negative average profit rates. These industries with negative profit rates are domestic service industries that are not subject to international competition.

There are eight six-digit NAICS industries, covering all establishments in those industries covered by the general section of the ETS, with cost-to-profit ratios above 10 percent:

1. NAICS 221118—Other Electric Power Generation, 23.97 percent;

2. NAICS 488119—Other Airport Operations, 18.41 percent;

3. NAICS 488410—Motor Vehicle Towing, 15.75 percent;

4. NAICS 488490—Other Support Activities for Road Transportation, 14.32 percent;

5. NAICS 713920—Skiing Facilities, 13.16 percent; and

[60] This cost advantage may be exaggerated or non-existent in many cases (see the discussion directly below in the text in Caveat 2).

[61] Several occupational groups less able to avoid exposure to SARS–CoV–2 infection exhibited significantly higher rates of absenteeism in March–April 2020 compared to earlier periods (Groenewold et al., July 10, 2020).

[62] For a discussion of turnover (*i.e.* whether the ETS could affect the likelihood that an employee will remain with an employer, either because the imposition of a vaccine requirement will lead some employees to leave and find employment at an establishment not subject to the ETS, or, alternatively, to stay due to a preference for enhanced COVID–19 safety procedures), please see the cost section (Section III.d.) of this economic analysis.

[63] By OSHA's calculation, 524 out of the 546 six-digit NAICS covered by the ETS.

6. NAICS 713940—Fitness and Recreational Sports Centers, 12.33 percent;

7. NAICS 713120—Amusement Arcades, 11.18 percent; and

8. NAICS 488320—Marine Cargo Handling, 10.03 percent.

The average profit rate reported over the 14 years for which OSHA has profit data for all the NAICS affected by the ETS is 4.2 percent. All of the eight NAICS industries with a cost-to-profit ratio above the 10 percent threshold report an annual profit rate below one percent—75 percent or more below the overall average for all NAICS covered by the ETS. These eight industries all provide domestic services and are not subject to international competition.

The fact that the covered firms in these 22 NAICS industries (the 14 with negative cost-to-profit ratios and the 8 with more sustainable cost-to-profit ratios) exceeded the profit screen suggests that they might in theory have difficulty paying for the costs of the ETS out of profits gained over the six-month duration of the ETS if they had no savings or access to capital, but even if that were true it would be highly unlikely to place the firms in financial jeopardy. OSHA examines these industries more closely below, but before even considering the reasons in NAICs-specific analysis it is important to consider the larger context. For the ETS to threaten the economic solvency of these firms, the following 3 conditions must apply:

1. These firms must *not* enjoy certain cost savings and positive economic impacts from the ETS that would partially or totally offset their costs. This condition is questionable because of the estimated 25 percent of employers sampled that reported voluntarily imposing a vaccine mandate and the substantial number more contemplating the voluntary adoption of such a mandate. They can be expected to base their decisions, partly or entirely, on anticipated cost savings or positive economic impacts (which would reduce or eliminate their risk of insolvency due to the ETS).

2. These firms (all with 100 or more employees) must *not* be able to raise prices to cover ETS costs because of the threat that smaller firms in their NAICS industry, not covered by the ETS, could underprice them and take away their business. This condition is unlikely or limited because of the economies of scale the larger firms enjoy and the fact that the smaller firms out of necessity tend to serve a market niche not in direct competition with the larger firms. Also, there is a severe limit to the extent that firms with fewer than 100 employees can take away significant portions of business from the larger firms without becoming subject to the requirements of the rule themselves. If the larger firms do not feel threatened by being underpriced by smaller firms in these NAICS industries, then they could raise prices an average of less than 0.05 percent [64] to cover the cost of the ETS—a small fraction of the 1.0 percent of revenues threshold (beneath which OSHA has determined that economic feasibility is not a concern).

3. These firms must *not* generate sufficient profits or have adequate borrowing capacity during the six months the ETS is in force to cover the costs of the ETS. There are several reasons to doubt that this condition broadly applies. First, the estimates of business profits come from corporate balance sheet data that firms report to the IRS. But, as previously noted, it is generally the case that firms have an incentive to minimize their tax burden, and it is reasonable to expect that some of the reported accounting data may have been strategically adjusted to reduce reported profits and their associated tax implications. Another point concerning the IRS data is that they include the negative profits of firms that are going out of business or have since gone out of business. To the extent that these points are true, many or most of the covered firms in these NAICS industries (still in business) actually would generate sufficient profit to cover the cost of the ETS. A related point is that for this condition to apply, the firms must not be able to borrow the money to pay for the costs of the ETS. Recall, however, that these are all large firms with 100+ employees. It is reasonable to expect that many or most firms of this size in the 22 NAICS industries at issue either have available funds or could obtain a short-term loan to cover costs equal to the 0.01 to 0.11 percent of revenues that these firms would incur over the six-month period that OSHA assumes the ETS will remain in effect. Firms of this size normally have banking relationships and some unencumbered assets. They also have access to national and international capital markets. If these firms can borrow funds to pay for the ETS, then the profit restriction doesn't matter.

Finally, OSHA anticipates concern that limiting the scope of the ETS to employers with 100 or more employees will somehow put these larger firms in economic jeopardy from the smaller firms to which the ETS does not currently apply. This is highly improbable for several reasons discussed earlier, including the fact that these are large employers with advantages of economies of scale and access to capital and the fact that this is a temporary standard that would result, at most, in marginal impacts over 6 months (on average, equal to costs of 0.02 percent of revenues, which, again, translates to a cost increase of a penny on a fifty dollar item).

But even that misses the main point: Economic feasibility refers to the industry, not to the firm. OSHA must construct a reasonable estimate of compliance costs and demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry, even if it does portend disaster for some marginal firms (*Lead I,* 647 F.2d at 1272). In the (again) highly unlikely event that individual firms exit an industry and are replaced by other firms in the industry, then the ETS would preserve the economic feasibility of the covered industries. If an employer covered by this standard actually had to increase its prices slightly to account for the cost of this standard, there are two potential groups of smaller businesses that could seek to supplant the covered firms. The first group of businesses are much smaller than the covered firms. Those businesses, however, will typically have higher costs and prices to begin with due to their scale disadvantages to the larger firms. The larger firm's small price increases attributable to this ETS would not be likely to create an actionable competitive advantage for this group of smaller businesses. The second group of businesses are those closer in size to the 100-employee cutoff. If the marginal price increases did actually cause some of the larger firms to fail and the slightly smaller firms to take their place, the industry itself would not suffer a massive dislocation or be imperiled. And, of course, if all of the firms in an industry are large employers with 100 or more employees, no competitive disadvantage from within the industry would exist (even hypothetically), and there would be no question that they could cover the cost of ETS by raising prices to customers accordingly.

Although the preceding discussion demonstrates that the ETS is economically feasible, OSHA has provided an additional examination of each of the NAICS that have crossed the profit screen (again noting that none of

[64] If not underpriced by smaller firms, covered firms in the 8 NAICS industries reporting ETS costs above 10 percent of profits could cover these costs by raising prices an average of 0.08 percent (highest, 0.11 percent); covered firms in the 14 NAICS industries reporting negative profits could cover ETS costs with a price increase of 0.01 percent (highest, 0.02 percent).

these failed the revenue screen): The eight NAICS industries with positive profit ratios but profit rates below 1 percent.

1. NAICS 221118—Other Electric Power Generation, 23.97 Percent

This U.S. industry comprises establishments primarily engaged in operating electric power generation facilities (except hydroelectric, fossil fuel, nuclear, solar, wind, geothermal, biomass). These facilities convert other forms of energy, such as tidal power, into electric energy. The electric energy produced in these establishments is provided to electric power transmission systems or to electric power distribution systems.

Using tides to generate power is not yet economically viable, according to one source, because ''[t]otal availability of tidal power is restricted by its relatively high cost and limited number of sites having high flow velocities and tidal ranges,'' although ''with [ ] recent advancements in tidal technologies, the total availability of tidal power in terms of turbine technology as well as design may be higher than before, and the economic costs may be reduced significantly to competitive levels.'' In support, in the same article, ''recent reports state that the UK, which has the largest tidal and wave resource in Europe, is capable of harnessing up to 153GW of tidal power capacity with the help of three types of technologies and thus meeting 20% of current UK electricity demand and reducing carbon emissions. Hence it is evident that wave and tidal energy could contribute more to the increasing electricity demands across the globe.'' [65]

At the time OSHA obtained the most recent NAICS data, there were 7 affected entities in this NAICS industry. The entities in this NAICS industry include firms like Berkshire Hathaway Energy Company, (with annual sales of $19.8 billion, whose ''portfolio consists of locally managed business that share a vision for a secure and sustainable energy future''); Dominion Energy (with annual sales of $13.4 billion); and other leading firms in this industry including some of the largest power generation companies in the US (See NAICS Association, 2018a; NAICS Association 2018d; and NAICS Association 2018e).

As this NAICS industry is not yet viable, (in the United States, at least), it is to be expected that revenues and profits would be low. In fact, OSHA believes the best way to view this industry is as a series of incredibly well-funded start-up companies during the investment phase of the business, where short-term losses are expected and offset with the anticipation of enormous revenue growth potential (in an acknowledged very limited energy market.) Given these factors, OSHA's typical revenue and profit screen are a poor predictor of future viability with respect to this NAICS industry (although, as pointed out, this NAICS industry, like all other NAICS industries, falls well below the revenue screen threshold). The estimated cost of this ETS per firm is $866 in this NAICS industry, which equals about 11 cents per hundred dollars of revenue over a limited six-month duration. OSHA concludes that this industry will be able to withstand this small cost in order to keep its workers protected during the pandemic.

2. NAICS 488119—Other Airport Operations, 18.41 Percent [66]

The services this industry offers are integrated into a particular geographic location and entail specific tasks, such as parking and baggage handling services, that must be done to ensure the proper functioning of airports, thus negating the potential for substitution during the 6 month period that OSHA is assuming the ETS will be in effect for economic purposes. In addition, because these are services that need to be done in particular domestic locations (*i.e.,* airports), there is no risk of international competition.

3. NAICS 488410—Motor Vehicle Towing, 15.75 Percent [67]

The actual cost impacts on this industry are likely significantly overstated to the extent that most employees performing towing services ride alone in their trucks and their services do not typically require exposure to others. In the event that individual large towing firms are concerned about economic impacts, it would not be difficult to structure their employee interactions with the company and customers to take advantage of the scope restrictions. Moreover, the primary services this industry offers involve the use of specialized vehicles designed uniquely for towing, thus lowering the risk of substitution. In addition, because these services are geographically based, there is no risk of international competition.

4. NAICS 488490—Other Support Activities for Road Transportation, 14.32 Percent [68]

This industry offers services that must be done to ensure proper operation of roadways (for example, bridge, tunnel, and highway operations, pilot car services (*i.e.,* wide load warning services), driving services (*e.g.,* automobile, truck delivery), and truck or weighing station operations), thus negating the potential for substitution. In addition, because these services need to be done in particular domestic locations (*i.e.,* roadways), there is no risk of international competition.

5. NAICS 713920—Skiing Facilities, 13.16 Percent [69]

This industry caters to a wealthy clientele who ensure an inelastic demand easily capable of absorbing any fractional increases attributable to this ETS.[70] In addition, skiing is done outdoors, which will incentivize clientele to continue engaging in this particular activity in lieu of indoor substitutions, during the pandemic. Finally, there is little to no risk of international competition from foreign ski resorts because the added and substantial costs of international travel outweigh the costs associated with marginally higher prices resulting from the ETS.

6. NAICS 713940—Fitness and Recreational Sports Centers, 12.33 Percent [71]

As these settings are generally located close to where clients live or work, there is no risk of international competition. Some of the largest employers in this industry have already responded to customer feedback by not only requiring employees to be vaccinated, but also

[65] See Walker, January 22, 2013.

[66] This U.S. industry comprises establishments primarily engaged in (1) operating international, national, or regional airports, or public flying fields or (2) supporting airport operations, such as rental of hangar space, and providing baggage handling and/or cargo handling services.

[67] This industry comprises establishments primarily engaged in towing light or heavy motor vehicles, both local and long-distance. These establishments may provide incidental services, such as storage and emergency road repair services.

[68] This industry comprises establishments primarily engaged in providing services (except motor vehicle towing) to road network users.

[69] This industry comprises establishments engaged in (1) operating downhill, cross country, or related skiing areas and/or (2) operating equipment, such as ski lifts and tows. These establishments often provide food and beverage services, equipment rental services, and ski instruction services. Four season resorts without accommodations are included in this industry.

[70] See Brown, January 19, 2017, ''[o]f the 9.4 million skiers in the U.S., more than half earn a salary higher than $100,000. For some context, only 20 percent of American households have a combined income of $100K. . . .'')

[71] This industry comprises establishments primarily engaged in operating fitness and recreational sports facilities featuring exercise and other active physical fitness conditioning or recreational sports activities, such as swimming, skating, or racquet sports.

members.[72] This suggests both that the costs estimates attributed to the ETS are overstated for these employers because higher levels of compliance may have already occurred than projected in OSHA's analysis, and that the ETS requirements reflect more of an industry trend than a threat to the existence of the industry.

7. NAICS 713120—Amusement Arcades, 11.18 Percent[73]

This industry caters to a select clientele who have chosen to engage in leisure activities in the unique settings offered by the industry, thus negating the likelihood for substitution. In addition, because these settings are localized, there is no risk of international competition.

8. NAICS 488320—Marine Cargo Handling, 10.03 Percent[74]

The services this industry offers are integrated into a particular location and entail specific tasks, such as loading and unloading services at ports and harbors, longshoremen services, marine cargo handling services, ship hold cleaning services, and stevedoring services, that must be done to ensure the proper movement of cargo off of and onto ships, thus negating the potential for substitution. In addition, because these are services that need to be done in particular domestic locations (*e.g.,* docks), there is no risk of international competition.

As with towing, the actual cost impacts on this industry are likely significantly overstated to the extent that some of the employees may be able to perform their work exclusively outdoors.

The Fourteen NAICS Industries With Negative Profit Ratios

1. Air Transportation[75]

NAICS 481111 (Scheduled Passenger Air Transportation), NAICS 481112 (Scheduled Freight Air Transportation), NAICS 481211 (Nonscheduled Chartered Passenger Air Transportation), NAICS 481212 (Nonscheduled Chartered Freight Air Transportation), NAICS 481219 (Other Nonscheduled Air Transportation).

This group of NAICS industries is comprised of U.S. industries that primarily engage in providing air transportation. There is little to no risk of substitution for this group of NAICS industries. Air transportation provides unique and important benefits that cannot be substituted via other forms of transportation (e.g., rail, freight, bus). (See ATAG, September 2005). To this end, air transportation is often the speediest means of transporting passengers and cargo, giving it a unique purpose that cannot be met by other forms of transport. It should be noted that the five NAICS in this group of industries are the only NAICS in NAICS 4811 (Scheduled Air Transportation) and 4812 (Nonscheduled Air Transportation). The other industries in NAICS 48 (Transportation) do not provide air transportation (See NAICS Association, 2018b). This further reduces the risk of substitution, as all five NAICS at issue have a negative profit ratio and therefore face similar challenges that appear to be endemic to air transportation. Firms in this industry that have been able to weather the pandemic this long are typically highly capitalized or have access to loans, so it is highly likely that they could also weather the temporary marginal costs of OSHA's ETS.

There is also no risk of international competition with respect to this group of NAICS industries because any workers, whether they work for an international company or not, who are in the US, are subject to US laws, including the ETS, and foreign air carriers will need to follow the ETS for those workers. In addition, OSHA suspects that any smaller foreign air carriers will not have an incentive to expand their routes significantly or change their routes to domestic US routes to take advantage of the 100-employee cutoff in the ETS in the 6-months the ETS is assumed to be in effect.

2. Telecommunications[76]

NAICS 517311 (Wired Telecommunications Carriers), NAICS 517312 (Wireless Telecommunications Carriers (except Satellite), NAICS 517410 (Satellite Telecommunications), NAICS 517911 (Telecommunications Resellers), NAICS 517919 (All Other Telecommunications).

This group of NAICS industries is entirely comprised of U.S. industries, except for NAICS 517410 (Satellite Telecommunications). All of these industries provide specialized unique services in the telecommunications industry that require specialized unique knowledge and are thus resistant to substitution. While it is perhaps

[72] See Jackson, August 2, 2021 ''Equinox also noted in the press release that 'an overwhelming majority of members' have expressed support for a vaccination requirement for entry to Equinox clubs.''

[73] This industry comprises establishments primarily engaged in operating amusement (except gambling, billiard, or pool) arcades and parlors.

[74] This industry comprises establishments primarily engaged in providing stevedoring and other marine cargo handling services (except warehousing).

[75] NAICS 481111 (Scheduled Passenger Air Transportation) provides air transportation of passengers or passengers and freight over regular routes and on regular schedules, including commuter and helicopter carriers (except scenic and sightseeing). NAICS 481112 (Scheduled Freight Air Transportation) provides air transportation of cargo without transporting passengers over regular routes and on regular schedules, including scheduled air transportation of mail on a contract basis. NAICS 481211 (Nonscheduled Chartered Passenger Air Transportation) provides air transportation of passengers or passengers and cargo with no regular routes and regular schedules. NAICS 481212 (Nonscheduled Chartered Freight Air Transportation) provides air transportation of cargo without transporting passengers with no regular routes and regular schedules. NAICS 481219 (Other Nonscheduled Air Transportation) provides air transportation with no regular routes and regular schedules (except nonscheduled chartered passenger and/or cargo air transportation). These establishments provide a variety of specialty air transportation or flying services based on individual customer needs using general purpose aircraft.

[76] NAICS 517311 (Wired Telecommunications Carriers) comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services; wired (cable) audio and video programming distribution; wired broadband internet services; and, by exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry. NAICS 517312 (Wireless Telecommunications Carriers (except Satellite)) comprises establishments primarily engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular phone services, paging services, wireless internet access, and wireless video services. NAICS 517410 (Satellite Telecommunications) comprises establishments primarily engaged in providing telecommunications services to other establishments in the telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications. NAICS 517911 (Telecommunications Resellers) comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. NAICS 517919 (All Other Telecommunications) comprises establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation, and also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems, as well as establishments providing internet services or Voice over internet protocol (VoIP) services via client-supplied telecommunications connections.

possible that different forms of telecommunications might be substituted for one another (e.g., the substitution of wired telecommunications carriers for wireless telecommunications carriers), the reality is that these different forms exist separately and feed different markets and customer needs that are independent of the ETS. Moreover, the five NAICS in this group of industries are the only NAICS in NAICS 5173 (Wired and Wireless Telecommunications Carriers), NAICS 5174 (Satellite Telecommunications), and NAICS 5179 (Other Telecommunications). The other industries in NAICS 51 (Information) are not engaged in telecommunications (NAICS Association, 2018c). This further reduces the risk of one industry substituting for the others, as all five NAICS at issue have a negative profit ratio and therefore face similar challenges that appear to be endemic to telecommunications.

Moreover, three of the five NAICS industries in this group (NAICS 517311, 517312, 517410) operate or control the infrastructure needed for engaging in the particular type of telecommunications in which those industries engage. This not only fully negates the risk of substitution, but also negates the risk of international competition for these industries.

The other two industries in the group apparently do not operate or control the infrastructure needed for telecommunications. However, the telecommunications industry faces strict state and federal licensing requirements, which severely limit the risk of competition both internationally and from smaller firms seeking to take advantage of the ETS's 100-employee cutoff. (See FCC, 2014; FCC, October 12, 2021a; FCC, October 12, 2021b; Caltrans, October 12, 2021; and UTC, October 12, 2021).

3. Car and Equipment Rental [77]

NAICS 532111 (Passenger Car Rental), NAICS 532112 (Passenger Car Leasing), NAICS 532120 (Truck, Utility Trailer), and RV (Recreational Vehicle) Rental and Leasing) NAICS 532310 (General Rental Centers).

This group of industries rent motor vehicles (NAICS 532111, 532112, 532120) or equipment (NAICS 532310), for example, audio visual equipment, contractors' and builders' tools and equipment, home repair tools, lawn and garden equipment, moving equipment and supplies, and party and banquet equipment and supplies, to individuals and businesses, for personal and professional use. There is no risk of substitution with respect to these industries, as these industries rent specific items to those who want to use them. There is also no risk of foreign competition with respect to these industries, as consumers and businesses rent and pick up vehicles, as well as the type of equipment offered for rent by NAICS 532310, from specific locations, including car rental and other rental centers.

These industries have not been hard hit by the pandemic, as many consumers have turned from group travel to individual transportation. For example, RV rentals and leasing has soared during the pandemic, which is not reflected in the pre-pandemic profit and revenue data available for this analysis.[78]

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[77] NAICS 532111 (Passenger Car Rental) comprises establishments primarily engaged in renting passenger cars without drivers, generally for short periods of time. NAICS 532112 (Passenger Car Leasing) comprises establishments primarily engaged in leasing passenger cars without drivers, generally for long periods of time. NAICS 532120 (Truck, Utility Trailer, and RV (Recreational Vehicle) Rental and Leasing comprises establishments primarily engaged in renting or leasing, without drivers, one or more of the following: Trucks, truck tractors, buses, semi-trailers, utility trailers, or RVs (recreational vehicles). NAICS 532310 (General Rental Centers) comprises establishments primarily engaged in renting a range of consumer, commercial, and industrial equipment. Establishments in this industry typically operate from conveniently located facilities where they maintain inventories of goods and equipment that they rent for short periods of time. The type of equipment that establishments in this industry provide often includes, but is not limited to: Audio visual equipment, contractors' and builders' tools and equipment, home repair tools, lawn and garden equipment, moving equipment and supplies, and party and banquet equipment and supplies.

[78] See Park, January 23, 2021.

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V. Additional Requirements

A. Regulatory Flexibility Act

Whenever an agency is required by the Administrative Procedure Act, 5 U.S.C. 553, or another law, to publish a general notice of proposed rulemaking, the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., requires the agency to prepare an initial regulatory flexibility analysis (IRFA). 5 U.S.C. 601(2), 603(a). Since this ETS ''shall serve as a proposed rule'' for a final standard under section 6(c)(3) of the OSH Act, it is treated as a general notice of proposed rulemaking under the RFA. An agency may waive or defer the IRFA in the event a rule is promulgated in response to an emergency that makes compliance with the requirements of section 603 impracticable. 5 U.S.C. 608(a). The agency hereby certifies that compliance with the IRFA requirement is impracticable under the circumstances. OSHA prepared this ETS on an expedited basis in response to a national emergency affecting the lives and health of the nation's workers; the IRFA is inherently a relatively lengthy process that would be impracticable to undertake for a standard of such broad applicability in the limited time available. Because OSHA is not preparing an IRFA for the ETS, the agency is also not required to convene a small entity panel under section 609(b).

B. Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1501 et seq.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1532, requires agencies to assess the anticipated costs and benefits of a rule before issuing ''any general notice of proposed rulemaking'' that includes a Federal mandate that may result in expenditures in any one year by state, local, or Tribal governments, or by the private sector, of at least $100 million, adjusted annually for inflation. The assessment requirement also applies to ''any final rule for which a general notice of proposed rulemaking was published.'' Although no general notice of proposed rulemaking was published, the agency has analyzed the ETS's economic feasibility and health impacts in Section IV.B. of this preamble (*Economic Analysis*) and Health Impacts Appendix (OSHA, October 2021c).

C. Executive Order 13175

Section 5 of E.O. 13175, on Consultation and Coordination with Indian Tribal Governments, requires agencies to consult with tribal officials early in the process of developing regulations that: (1) Have tribal implications, that impose substantial direct compliance costs on Indian governments, and that are not required by statute; or (2) have tribal implications and preempt tribal law. 65 FR 67249, 67250 (Nov. 6, 2000). E.O. 13175 requires that such consultation occur to the extent practicable. Given the expedited nature of issuing the ETS, it was not practicable for OSHA to consult and incorporate non-federal input prior to promulgation of the standard. OSHA commits to meaningful consultation with tribal representatives after publication of the ETS and during the comment period before finalizing any permanent standard. Such consultation will be consistent with the Administrative Procedure Act.

D. National Environmental Policy Act

OSHA has reviewed this ETS according to the National Environmental Policy Act (NEPA) of 1969, 42 U.S.C. 4321 et seq., the regulations of the Council on Environmental Quality, 40 CFR chapter V, subchapter A, and the Department of Labor's NEPA procedures, 29 CFR part 11. As a result of this review, the agency has determined that the rule will have no significant impact on air, water, or soil quality; plant or animal life; the use of land; or other aspects of the external environment. Although the ETS contains testing requirements, and test kits and supplies can generate some additional materials that will enter the waste stream, the impact of this ETS will be minimal. As discussed in more detail in *Technological Feasibility* (Section IV.A. of this preamble), there is already a surplus of available tests, and projected production of COVID–19 tests will be more than sufficient to meet demands for testing created as a result of the rule. Therefore, tests used for purposes of or for compliance with this ETS are not being produced as a result of this standard, and the standard will not generate significant new streams of waste beyond what would be generated in the absence of the standard.

E. Congressional Review Act

This ETS is considered a major rule under the Congressional Review Act (CRA), 5 U.S.C. 801 et seq. Section 801(a)(3) of the CRA normally requires a 60-day delay in the effective date of a major rule. 5 U.S.C. 801(a)(3), 804(2). However, section 808(2) of the CRA 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 are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 808(2). OSHA finds that there is good cause to make this rule effective upon publication because notice and public procedure with respect to this ETS are both impracticable and contrary to the public interest, given the expedited timeline on which this standard was developed and the grave danger threatening workers' lives and health (see *Grave Danger* and *Need for the ETS*, both in Section III. of this preamble). Congress authorized OSHA to take swift action in promulgating an ETS to address this type of grave danger, and provided explicitly that an ETS is effective upon publication, 29 U.S.C. 655(c)(1); delaying the effective date of such an expedited process would thwart that purpose. It is specifically because of the emergency nature of this rulemaking that the OSH Act allows for OSHA to proceed without the extensive public input the agency normally solicits in issuing occupational safety and health standards. 29 U.S.C. 655(c)(1). For rules to which section 808(2) applies, the agency may set the effective date. In this case, consistent with the OSH Act requirement cited above, the ETS takes immediate effect upon publication in the **Federal Register**.

F. Administrative Procedure Act

The Administrative Procedure Act (APA) normally requires notice and comment, and a 30-day delay of the effective date of a final rule, for recordkeeping and reporting regulations promulgated under section 8(c) of the OSH Act. 29 U.S.C. 657(c); 5 U.S.C. 553(b), (d). This ETS contains recordkeeping and reporting requirements tailored to address COVID–19 illness. To the extent that these requirements are not already

exempt from the APA's requirements for notice and comment under section 6(c) of the Act (29 U.S.C. 655(c)), OSHA invokes the ''good cause'' exemption to the APA's notice requirement because the agency finds that notice and public procedure are impracticable and contrary to the public interest under 5 U.S.C. 553(b)(B). As explained in more detail in *Grave Danger* and *Need for the ETS* (both in Section III. of this preamble), this finding is based on the critical importance of implementing the requirements in this ETS, including the recordkeeping and reporting provisions, as soon as possible to address the grave danger that COVID–19 presents to workers.

As noted above, the ETS is required by the OSH Act to take immediate effect upon publication. 29 U.S.C. 655(c)(1). For that reason, and the underlying public health emergency that prompted this ETS as discussed above, OSHA finds good cause to waive the normal 30-day delay in the effective date of a final rule from the date of its publication in the **Federal Register**. See 5 U.S.C. 553(d)(3). OSHA notes, however, that OSHA does not require compliance with any provision of the ETS within the first 30 days after it becomes effective.

G. Consensus Standards

OSHA must consider adopting an existing national consensus standard that differs substantially from OSHA's standard if the consensus standard would better effectuate the purposes of the Act. See section 12(d)(1) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C.A. 272 Note); see also 29 U.S.C. 655(b)(8).

OSHA considered incorporation of ASTM F3502–21 in this ETS, as required. However, the agency has insufficient evidence to make a general finding of feasibility at this time. The agency notes that face coverings that meet ASTM F3502–21 criteria also meet the definition of ''face coverings'' in this ETS (see the discussion of this issue in *Summary and Explanation*, Section VI. of this preamble). The agency has asked questions about this topic to gather additional information.

H. Executive Order 13045

Executive Order 13045, on Protection of Children from Environmental Health Risks and Safety Risks, requires that Federal agencies submitting covered regulatory actions to OIRA for review pursuant to Executive Order 12866 must provide OIRA with (1) an evaluation of the environmental health or safety effects that the planned regulation may have on children, and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency (62 FR 19885 (April 23, 1997)). Executive Order 13045 defines ''covered regulatory actions'' as rules that may (1) be economically significant under Executive Order 12866, and (2) concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children. Because OSHA has no reason to believe that the risk from COVID–19 disproportionately affects children, the ETS is not a covered regulatory action and OSHA is not required to provide OIRA with further analysis under section 5 of the executive order. However, to the extent children are exposed to COVID–19 either as employees or at home as a result of family members' workplace exposures to COVID–19, the ETS should provide some protection for children.

I. Federalism

The agency reviewed this ETS according to Executive Order 13132, on Federalism, which requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States before taking actions that would restrict States' policy options, and take such actions only when clear constitutional authority exists and the problem is of national scope. 64 FR 43255 (August 10, 1999). The Executive Order generally allows Federal agencies to preempt State law only as provided by Congress or where State law conflicts with Federal law. In such cases, Federal agencies must limit preemption of State law to the extent possible.

The Occupational Safety and Health Act is an exercise of Congress's Commerce Clause authority, and under Section 18 of the Act, 29 U.S.C. 667, Congress expressly provided that States may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards. OSHA refers to States that obtain Federal approval for such plans as ''State Plans.'' Occupational safety and health standards developed by State Plans must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. As discussed below, State Plans must submit to Federal OSHA for approval, standards that differ from Federal standards addressing the same issues, in order for such standards to become part of the OSHA-approved State Plan. Subject to these requirements, State Plans are free to develop and enforce their own occupational safety and health standards.

This ETS complies with E.O. 13132. The problems addressed by this ETS for COVID–19 are national in scope. As explained in *Grave Danger* (Section III.A. of this preamble), employees face a grave danger from exposure to COVID–19 in the workplace. Employees across the country face the danger of exposure to COVID–19 at work, and as explained in *Need for the ETS* (Section III.B. of this preamble), a national standard is needed to protect workers from the grave danger of COVID–19 by strongly encouraging vaccination and limiting the presence of COVID–19 positive workers in the workplace through testing and to ensure that a clear and consistent baseline approach is taken across the country to protect them. The SARS–CoV–2 virus is highly communicable and infects workers without regard to state borders, making a national approach necessary. Accordingly, the ETS establishes minimum requirements for employers in every State to protect employees from the risks of exposure to COVID–19.

In States without OSHA-approved State Plans, Congress provides for OSHA standards to preempt State occupational safety and health standards for issues addressed by the Federal standards. In these States, this ETS limits State policy options in the same manner as every standard promulgated by the agency. Furthermore, as discussed in the *Summary and Explanation* for *Purpose*, nothing in the ETS is intended to limit generally applicable public health measures instituted by state or local governments that go beyond, and are not inconsistent with, the requirements of the ETS. (See *Summary and Explanation for Purpose*, Section VI.A. of this preamble); *Gade* v. *National Solid Wastes Management Ass'n*, 505 U.S. 88, 107 (1992). In States with OSHA-approved State Plans, this ETS does not significantly limit State policy options. Any special workplace problems or conditions in a State with an OSHA-approved State Plan may be dealt with by that State's standard, provided the standard is at least as effective as this ETS.

As discussed in the *Summary and Explanation for Purpose* in this preamble, OSHA has included a provision that states the purpose of this ETS, as well as OSHA's intent to preempt all inconsistent State and local requirements that relate to the issues addressed by this ETS. (See section 1910.501(a); *Summary and Explanation* for *Purpose*, Section VI.A. of this preamble). This includes State and local

requirements banning or limiting the authority of employers to require vaccination, face covering, or testing. As discussed in that section, such State and local bans would be preempted by this ETS, even in States with OSHA-approved State Plans, because such bans are not approved by federal OSHA as part of the State Plan and could not be approved, because such bans are clearly not as effective—and, indeed, are contrary to—the federal ETS. See *Indust. Truck Ass'n* v. *Henry*, 125 F.3d 1305, 1311 (9th Cir. 1997).

J. State Plans

When Federal OSHA promulgates an emergency temporary standard, States and U.S. Territories with their own OSHA-approved occupational safety and health plans (''State Plans'') must either amend their standards to be identical or ''at least as effective as'' the new standard, or show that an existing State Plan standard covering this area is ''at least as effective'' as the new Federal standard. 29 CFR 1953.5(b). This ETS imposes new requirements to protect workers across the nation from COVID–19. Adoption of this ETS, or an ETS that is at least as effective as this ETS, by State Plans must be completed within 30 days of the promulgation date of the final Federal rule, and State Plans must notify Federal OSHA of the action they will take within 15 days. The State Plan standard must remain in effect for the duration of the Federal ETS. As noted above in *Federalism* (Section V.I. of this preamble), this ETS preempts all State and local requirements, including in States with State Plans, that ban or limit the authority of employers to require vaccination, face covering, or testing. (See also the *Summary and Explanation* for *Purpose*, Section VI.A. of this preamble). As with all non-identical State Plan standards, OSHA will review any comparable State standards to determine whether they are at least as effective as this ETS. A State Plan standard that prohibits employers from requiring vaccination would not be at least as effective as this ETS because OSHA has recognized in this ETS that vaccination is the most protective policy choice for employers to adopt to protect their workplaces.

Of the 28 States and Territories with OSHA-approved State Plans, 22 cover both public and private-sector employees: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. The remaining six States and Territories cover only state and local government employees: Connecticut, Illinois, Maine, New Jersey, New York, and the Virgin Islands.

K. Paperwork Reduction Act

I. Overview

The Emergency Temporary Standard (ETS) for COVID–19 Vaccination and Testing contains collection of information requirements 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, et seq., and OMB's regulations at 5 CFR part 1320. The PRA defines a *collection of information* to mean *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)). OSHA has determined an ETS is necessary to protect workers from the grave danger posed by COVID–19 and is issuing an ETS that amends 29 CFR 1910 subpart U to provide COVID–19 protections to workers of employers with 100 or more employees. Section 1910.501 contains collections of information necessary to effectuate the purpose of the ETS. The collections of information appear in paragraphs 1910.501(d), (e)(2), (e)(4), (f)(1), (g)(1), (g)(4), (h)(1), (j), (k)(1), (k)(2), (l)(1), and (l)(2). For a more comprehensive discussion of these provisions, see the sectional analysis earlier in this preamble. These information collections are applied by cross reference to other industries in regulations 29 CFR 1915.1501 (Shipyard Employment), 1917.31 (Marine Terminals), 1918.110 (Longshoring), 1926.58 (Construction), 1928.21 (Agriculture).[79]

Under the PRA, a Federal agency cannot conduct or sponsor a collection of information unless OMB approves it and the agency displays a currently valid OMB control number (44 U.S.C. 3507). Notwithstanding any other provision of law, if a collection of information does not display a currently valid control number, an employer shall not be subject to penalty for failing to comply with the collection of information (44 U.S.C. 3512). The PRA has special provisions for emergency situations that are applicable to this ETS. OMB may authorize a collection of information without regard to the normal clearance procedures if either (a) the relevant agency determines that the collection of information is essential to the mission of the agency and public harm is reasonably likely to result if normal clearance procedures are followed, or (b) the use of normal clearance procedures is reasonably likely to cause a statutory or court ordered deadline to be missed (44 U.S.C. 3507(j) and 5 CFR 1320.13). Because COVID–19 presents an ongoing public health threat to workers and American businesses, OSHA has requested the use of these emergency procedures for this ETS. In accordance with 44 U.S.C. 3507(j)(1), OMB approved the request and assigned this ETS an OMB control number that is valid for 180 days. Therefore, the information collection provisions contained within this ETS will take effect at the same time as all other provisions.

II. Summary of Information Collection Requirements

This information collection is summarized as follows.

1. *Title:* COVID–19 Vaccination and Testing Emergency Temporary Standard (29 CFR 1910, subpart U; 1915, subpart Z; 1917, subpart B; 1918, subpart K; 1926, subpart D; 1928, subpart B).

2. *Type of Review:* Emergency.

3. *OMB Control Number:* 1218–0278.

4. *Affected Public:* This rule applies to employers with a total of 100 or more employees except where the workplace is covered under the Safer Federal Workforce Task Force COVID–19 Workplace Safety: Guidance for Federal Contractors and Subcontractors; or in setting where the employee provides healthcare services or healthcare support services that falls under the requirements of 29 CFR 1910.502. This rule does not apply to employees of covered employers who work from home, exclusively outdoors, or who do not report to a workplace where other individuals such as coworkers or customers are present.

5. *Description of the ICR.* This ICR contains collections of information requirements for employers with 100 or more employees. The employer must establish, implement, and enforce a written mandatory vaccination policy that requires each employee to be fully vaccinated against COVID–19 unless the employer implements a policy that allows employees to choose between being fully vaccinated or both tested and wearing a face covering. Employers must determine employee vaccination status, and must require than any employees who are not vaccinated be tested for COVID–19 at least once every

[79] The ETS applies to agricultural establishments with 11 or more employees engaged on any day in hand-labor occupations in the field and agricultural establishments that maintain a temporary labor camp, regardless of how many employees are engaged on any day in hand-labor occupations in the field).

7 days. Employers must provide specified information to employees regarding COVID–19 vaccine efficacy, safety, and the benefits of being vaccinated, and must maintain a record of the COVID–19 vaccination status, proof of vaccination, and copies of employee COVID–19 test results, and the aggregate number of fully vaccinated employees at a workplace along with the total number of employees at that workplace.

6. *Number of respondents:* 1,858,935.
7. *Frequency:* Varies.
8. *Number of Responses:* 205,262,803.
9. *Estimated Burden Hours:* 79,720,444.
10. *Estimated Cost (Capital-operation and maintenance):* $1,383,751,520.

These totals are explained and supported in the agency's Supporting Statement as required by the PRA.

III. Request for Comment

Although the ETS takes effect immediately, with implementation dates specified in the Dates provision of this publication, it also serves as a temporary standard that can only be made permanent following an opportunity for public notice and comment. OSHA therefore invites the public to submit comments to OSHA on the proposed collections of information with regard to the following.

- Whether the proposed collections of information are necessary for the proper performance of the Agency's functions, including whether the information is useful.
- The accuracy of OSHA's estimate of the burden (time and cost) of the collections of information, including the validity of the methodology and assumptions used.
- The quality, utility, and clarity of the information collected.
- Ways to minimize the compliance burden on employers, for example, by using automated or other technological techniques for collecting and transmitting information.

Please submit comments related to the Paperwork Act analysis to OSHA in the PRA docket (Docket Number OSHA–2021–0008). Comments related to other parts of the ETS should be submitted to the rulemaking docket (Docket Number OSHA–2021–0007). OSHA will accept comments for 60 days on the information collection aspects of the rule. For instructions on submitting these comments to the rulemaking and/or PRA docket, see the sections of this **Federal Register** notice titled **DATES** and **ADDRESSES**.

References

Occupational Safety and Health Administration (OSHA). (2021c, October). Health Impacts of the COVID–19 Vaccination and Testing ETS. (OSHA, October 2021c)

VI. Summary and Explanation

A. Purpose

The ETS includes a sentence that states the purpose of the rule. The first part of the sentence in the paragraph indicates that the standard addresses the grave danger of COVID–19 in the workplace by establishing workplace vaccination, vaccination verification, face covering and testing requirements.

The second part of the sentence addresses the preemption of State and local laws, regulations, executive orders, and other requirements, by this Federal standard. It indicates OSHA's intention that the ETS address comprehensively the occupational safety and health issues of vaccination, wearing face coverings, and testing for COVID–19, and thus that the standard is intended to preempt States, and political subdivisions of States, from adopting and enforcing workplace requirements relating to these issues, except under the authority of a Federally-approved State Plan. In particular, OSHA intends to preempt any State or local requirements that ban or limit an employer's authority to require vaccination, face covering, or testing.

Preemption of such State and local requirements derives from section 18 of OSH Act and general principles of conflict preemption. See *Gade* v. *National Solid Wastes Management Ass'n*, 505 U.S. 88 (1992).[80] *Gade* clarified two important principles. First, section 18 expresses Congress' intent to preempt State workplace safety or health laws relating to issues on which Federal OSHA has promulgated occupational safety and health standards. Under section 18, a State can avoid preemption of such laws only if it submits and receives Federal approval for a State Plan for the development and enforcement of standards. OSHA-approved State Plans operate under authority of State law and must adopt occupational safety and health standards which, among other things, must be at least as effective in providing safe and healthful employment and places of employment as Federal standards. 29 U.S.C. 667.

[80] The Court held that the dual impact licensing statutes were preempted; however, no rationale commanded a majority. A four-justice plurality found that supplementary State regulation is impliedly preempted. Id. at 98–99. Justice Kennedy's concurrence would have found express preemption rather than implied preemption, Id. at 110–111, but otherwise agreed that ''in the OSH statute Congress intended to pre-empt supplementary state regulation.'' Id. at 113.

Second, State and local laws that do not constitute occupational safety or health laws because they are ''laws of general applicability'' that regulate workers and nonworkers alike are preempted only if they conflict with the federal standard. Laws of general applicability that are consistent with the federal standard are not preempted. *Gade*, 505 U.S. at 107.

While section 18 applies to every occupational safety and health standard that OSHA promulgates, this ETS raises particular concerns because of the current landscape of existing State and local requirements that may overlap with, or directly conflict with, the requirements of this ETS. As discussed in *Need for the ETS* (Section III.B. of this preamble), OSHA is adopting this ETS in response to an unprecedented health crisis that has resulted in a global pandemic severely impacting the health and wellbeing of people in the United States, and globally. This ETS is issued based on OSHA's determination that employees in the United States face a grave danger from workplace exposures to SARS–CoV–2, that the ETS is necessary to protect those workers, and that the measures for vaccination, vaccine verification, face coverings, and testing that this ETS requires will help ensure that workers covered by the ETS are protected from severe illness and death resulting from contracting COVID–19 in the workplace.

As explained in *Need for the ETS* (Section III.B. of this preamble), the lack of a national standard on this hazard has led to disparate State and local requirements, and this underscores the need for OSHA's ETS to provide clear and consistent protection to employees across the country. Over the past months, an increasing number of States have passed laws or enacted other requirements banning workplace vaccination policies that would mandate vaccination or require proof of vaccination status, thus prohibiting employers operating in those jurisdictions from implementing this proven method of protecting workers from the hazard of COVID–19 that is at the core of this ETS (see, *e.g.,* Texas Executive Order GA–40, October 11, 2021; Montana H.B. 702, July 1, 2021; Arkansas S.B. 739, October 4, 2021 and Arkansas H.B. 1977, October 1, 2021; AZ Executive Order 2021–18, Aug. 16, 2021). While some States' bans have focused on preventing local governments from requiring their public employees to be vaccinated or show proof of vaccination, the Texas, Montana, and Arkansas requirements apply to private employers as well. Likewise, some States and localities

have enacted requirements that prohibit businesses, government offices, schools or other public spaces from requiring that face coverings be worn (see, *e.g.,* Florida Executive Order 21–102, May 3, 2021; Texas Executive Order GA–34, March 2, 2021; Texas Executive Order GA–36, May 18, 2021). State and local requirements that prohibit employers from implementing employee vaccination mandates, or from requiring face coverings in workplaces, serve as a barrier to OSHA's implementation of this ETS, and to the protection of America's workforce from this deadly virus.

As discussed below, state restrictions of this kind are clearly preempted whether they take the form of direct workplace regulation or are part of a law of general applicability because they relate to the issues addressed by this standard and conflict with it. *Gade*, 505 U.S. at 99, 107. As is also discussed below, this is true even for State or local requirements that may not prevent employers from compliance with the ETS, but that prescribe or limit the employer's ability to mandate vaccination for its workforce as the employer's chosen means of compliance. See *Gade*, 505 at 107; see also *Geier* v. *American Honda*, 529 U.S. 861, 869, 875–886 (2000) (finding Department of Transportation (DOT) regulations preempted a State tort action where the state action ''upset the careful regulatory scheme established by federal law'' and placing weight on DOT's interpretation that such tort suit would be ''an obstacle to the accomplishment and execution'' of Agency objectives). An employer's choice to mandate vaccination is a critical aspect of this ETS, and state laws that remove that choice conflict with it.

Thus, to ensure that the ETS supplants the existing State and local vaccination bans and other requirements that could undercut its effectiveness, and to foreclose the possibility of future bans, OSHA has clearly defined the issues addressed by this section to encompass vaccination, face covering, and testing needed to protect against transmission of COVID–19 to employees in the workplace. To avoid ambiguity, OSHA has stated expressly that it intends this ETS to preempt all State and local workplace requirements that ''relate'' to these issues, except pursuant to a State Plan. 29 U.S.C. 667(b).

The ''unavoidable implication'' of section 18 is that because OSHA has adopted this ETS, States may no longer regulate these issues except with OSHA's approval and the authority of a Federally-approved State Plan. *Gade*, 505 U.S. at 99. As the Court explained, section 18 preempts States without approved plans from adopting or enforcing any laws that constitute, ''in a direct, clear and substantial way regulation of worker health and safety'' relating to an issue addressed by an OSHA standard. Id. at 107.

State and local requirements that ban or otherwise limit workplace vaccination, face covering, or testing clearly ''relate'' to the occupational safety and health ''issues'' that OSHA is regulating in this ETS. 29 U.S.C. 667(b). Such bans regulate key workplace COVID–19 protections that are encompassed by this ETS ''in a direct, clear and substantial way.'' *Gade*, 505 U.S. at 107. The direct effect of such bans is to prohibit employers from requiring employees to implement measures, such as vaccination requirements, face coverings, or testing. These workplace protective measures are covered by, and, in many circumstances required by, this ETS. For example, vaccination mandate bans directed at employers specifically bar them from requiring employee vaccination requirements for the purposes of protecting their workforce. Prohibitions on face covering mandates likewise directly prohibit individuals in positions of authority, including employers, from requiring face covering use.

Although the expressly stated purposes for State and local requirements banning or limiting employers from requiring vaccinations, face coverings, or testing may not be occupational safety and health,[81] this does not control their preemption under section 18 of the OSH Act. In assessing State and local requirements' impact on a federal statutory scheme, courts ''have refused to rely solely on the legislature's professed purpose and have looked as well to the effects of the law.'' *Gade*, 505 U.S. at 105; see also, *e.g., Perez* v. *Campbell*, 402 U. S. 637, 651–652 (1971) (''[A]ny state legislation which frustrates the full effectiveness of federal law is rendered invalid by the Supremacy Clause''); *Napier* v. *Atlantic Coast Line R. Co.*, 272 U.S. 605, 612 (1926) (pre-emption analysis does not depend on whether federal and State laws ''are aimed at distinct and different evils'' but whether they ''operate upon the same object'').

That a State has articulated a purpose other than, or in addition to, workplace health and safety would not divest the OSH Act of its preemptive force, because preemption law looks to the effects as well as the purpose of a State law, and thus a dual-impact State law cannot avoid OSH Act preemption simply because the regulation serves several objectives. *Gade*, 505 U.S. at 107 (holding ''a law directed at workplace safety is not saved from pre-emption simply because the State can demonstrate some additional effect outside of the workplace'' and ''[t]hat such law may also have a nonoccupational impact does not render it any less of an occupational standard for purposes of pre-emption analysis''). Thus, to the extent that the stated purpose of a requirement that bans or limits employers from requiring vaccinations, face coverings, or testing is something other than, or in addition to, occupational health, such laws, which have a specific and direct impact on worker health, are nevertheless preempted.

Further, section 18 preempts even ''nonconflicting'' State and local occupational safety and health requirements relating to the issues addressed by this standard. *Gade*, 505 U.S. at 98–99, 103; see id. at 100 (''state laws regulating the same issue as federal laws are not saved, even if they merely supplement the federal standard''). This is because OSHA '''pre-empts the field' for any nonapproved State law regulating the same safety and health issue.'' See *Gade*, 505 U.S. at 104, n. 2, citing *English* v. *General Electric. Co.*, 496 U.S. 72, 79–80, n.5 (''[F]ield preemption may be understood as a species of conflict pre-emption: A State law that falls within a pre-empted field conflicts with Congress' intent (either express or plainly implied) to exclude state regulation''); see also id. at 105 (discussing effect of field preemption). See generally *Geier*, 529 U.S. at 869, 875–886 (finding State law preemption where it ''upset the careful regulatory scheme established by federal law''); *Williamson* v. *Mazda Motor of Am., Inc.*, 562 U.S. 323, 330–36 (2011) (affirming the conflict pre-emption principle that ''a state law that stands as an obstacle to the accomplishment and execution of the full purposes and objectives of a federal law is pre-empted'' and finding preemption where State law interfered with ''significant objective'' of the federal regulation).

For example, the ETS would preempt State or local governments from

[81] The express purposes of such requirements banning or limiting employers from requiring vaccination, face coverings, or testing may often not relate to occupational safety and health. For example, Governor Greg Abbott's Texas face covering mandate ban in Executive Order GA–16, is based on alleged decreasing COVID–19 rates and the need to alleviate ''confusion,'' (Texas Executive Order GA–36, May 18, 2021); the stated purpose of Montana's vaccination mandate ban is to address health care privacy interests (Montana H.B. 702, July 1, 2021).

dictating that employers adopt a scheme of testing and face coverings that complies with 1910.501(g) and (i) of the ETS, but that bars employers from electing the preferred vaccine mandate alternative in paragraph (d), because this interferes with OSHA's significant regulatory objectives and its preemption of the field.[82] (*See Need for the ETS* (Section III.B. of this preamble) discussing that vaccination is the preferred compliance option under this rule because it is the most effective method of protecting workers from COVID–19). Likewise, the ETS would preempt such State or local occupational requirements, even to the extent that they may regulate employers with fewer than 100 employees, notwithstanding that the requirements in this ETS only apply to employers with more than 100 employees.

Case law is instructive on this point. In Gade, the Supreme Court found regulations implementing a State statute that required training for workers handling hazardous waste that went beyond, but did not conflict with, OSHA's hazardous waste training requirements to be preempted by the OSHA requirements. Id. Likewise, in *Industrial Truck Association Incorporated* v. *Henry*, the Ninth Circuit found that OSHA's hazard communication standard preempted California's Hazard Communication regulations that were not submitted to OSHA for approval through its State Plan, even to the extent that California's Hazard Communication rule regulated manufacturers and distributers who were excluded from coverage under federal OSHA's rule. *Indust. Truck Ass'n* v. *Henry*, 125 F.3d 1305, 1311–14 (9th Cir. 1997). In the same way, the ETS preempts all State and local requirements that bar or limit the ability of an employer to require workplace vaccination, testing, and face coverings to protected employees against COVID–19 in any respect, since OSHA has occupied the entire field of regulation on these issues.

OSHA's definition of the ''issue'' in this rule should be afforded weight, since the OSH Act vests OSHA with standard-setting responsibility and, therefore, the authority to determine which ''issues'' to address with occupational safety and health standards. See *Indust. Truck*, 125 F.3d at 1311 (relying on OSHA's regulation and statements in the preamble to identify the relevant ''issue'' for preemption purposes in OSHA's Hazard Communication standard).

Importantly, although OSHA's stated intention is to preempt conflicting State and local requirements relating to the issues addressed by this standard, OSHA recognizes that the OSH Act does not allow, and OSHA does not intend, for the ETS to preempt non-conflicting State or local requirements of general applicability. In *Gade*, the Supreme Court qualified its ruling by saving from preemption non-conflicting State and local ''laws of general applicability (such as laws regarding traffic safety or fire safety) that do not conflict with OSHA standards and that regulate the conduct of workers and nonworkers alike.'' *Gade*, 505 U.S. at 107. The Majority reasoned that, ''[a]lthough some laws of general applicability may have a 'direct and substantial' effect on worker safety, they cannot fairly be characterized as 'occupational' standards, because they regulate workers simply as members of the general public.'' Id.

During the pandemic, many States and municipal governments have adopted requirements intended to protect public health by helping to prevent the spread of COVID–19 in public spaces. These have included requirements mandating face coverings in indoor public spaces, including businesses, government buildings, and schools (see, *e.g.,* Baltimore City Health Department, August 10, 2021; Illinois Executive Order 2021–20, August 26, 2021; Hawai'i Emergency Proclamation, October 1, 2021). In addition, in recent months, some States and municipal governments have adopted requirements mandating that members of the public provide proof of vaccination or recent COVID–19 testing in order to enter restaurants, bars, or other businesses or public spaces (see, *e.g.,* NYC Emergency Executive Order 225, August 16, 2021 (mandating COVID–19 vaccination for most individuals for indoor entertainment, recreation, dining and fitness settings)). Requirements such as these apply to ''workers and nonworkers alike'' and ''regulate workers simply as member of the general public'' and are accordingly not preempted. *Gade*, 505 U.S.at 107.

Based on OSHA's observations and experience during the past year and a half that the pandemic has been ongoing, OSHA is confident that protective State and local regulations of general applicability that mandate face coverings or vaccination will complement, rather than interfere with OSHA's enforcement of the ETS, and also does not intend to preempt such requirements. Indeed, OSHA believes that such measures have significantly reduced the harmful effects of the pandemic and total fatalities. See Steel Institute of *NY* v. *The City of NY*, 716 F.3d 31, 38 (affording some weight to OSHA's view that municipal regulations governing construction cranes did not interfere with OSHA's regulatory scheme in its crane standards and ultimately adopted OSHA's view in finding these municipal regulations were not preempted by OSHA crane standards).[83]

In *Steel Institute*, the Second Circuit held that OSHA's crane regulations did not preempt New York City municipal regulations governing construction cranes, finding that such regulations were requirements of general applicability, notwithstanding their direct bearing on worker safety, because their primary purpose and effect was to preserve the safety of the general public, and they regulated workers and nonworkers alike. Id. The *Steel Institute* court noted the ''strong presumption against preemption when states and localities ''exercise[ ] their police powers to protect the health and safety of their citizens.'' Id. at 36, citing *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 475 (1996). The Second Circuit was also influenced by the clear danger presented to the public by unsafe crane operation. This is analogous to the situation here, because exposure to COVID–19 is a hazard that directly impacts everyone. Thus, generally applicable State and local mandates requiring face coverings or vaccination should not be preempted and should

[82] OSHA is aware that some States have adopted or are considering adopting such requirements, which this ETS would preempt (see, *e.g.,* Arkansas S.B. 739, October 4, 2021 and Arkansas H.B. 1977, October 1, 2021, which Arkansas Governor Asa Hutchinson allowed to became law without his signature, and which require employers in Arkansas to allow employees to opt out of vaccination for purposes of complying with federal vaccination requirements; see also Governor Hutchinson, October 13, 2021; Marr, October 7, 2021 (describing the Arkansas legislation and noting that other states may contemplate similar legislation)).

[83] OSHA's Cranes and Derricks in Construction rule directly discussed its expectations and intent regarding the preemptive effect of the rule, including that it was not intended to preempt generally applicable municipal regulations, such as building codes, which serve public safety purposes. Cranes and Derricks in Construction, 75 FR 47,906, 48,128 (August 9, 2010). This rule also includes a provision that requires employers to comply with State crane operator licensing requirements that meet the federal floor for crane operator certification in the rule. 29 CFR 1926.1427(c)(1). OSHA has also indicated that its rule would not preempt State or local requirements in other rulemakings. See e.g., 72 FR 7136, 7188 (Feb. 14, 2007) (Preamble to OSHA's most recent electrical safety standard) (''State and local fire and building codes, which are designed to protect a larger group of persons than employees,'' are not preempted); 29 CFR 1910.134(e) (requiring compliance with State and local laws by requiring ''a licensed health care professional'' to perform a medical evaluation of an employee's ability to use a respirator).

remain in effect, notwithstanding this ETS.[84]

On the other hand, as noted above, this standard will preempt requirements that conflict with it, regardless of whether the requirements are part of a law of general applicability.[85]

The effect of the ETS on State law requirements in State Plan States works somewhat differently. As previously noted, under section 18 of the OSH Act States that wish to assume responsibility for the development and enforcement of ''occupational safety and health standards relating to any occupational safety or health issue with respect to which a Federal standard has been promulgated'' may submit a State Plan to OSHA for approval. Id. section 667(b); see also id. section 667(c) (describing requirements for OSHA approval of State Plans on issues for which OSHA has adopted standards). There are 22 States and territories that have OSHA-approved State Plans for private employers, and 6 additional States and territories that have OSHA-approved State Plans for public employers only.

Under section 18(c)(2) of the OSH Act, State Plans are required to adopt and enforce occupational safety and health standards that are at least as effective as federal OSHA's requirements. Id. section 667(c)(2). In addition, the OSH Act requires that State Plans must cover State and local government employees (including, *e.g.,* State and local school systems within the scope of this rule), even though federal OSHA does not have coverage over such employees in States without OSHA-approved State Plans.

Once OSHA promulgates an ETS, OSHA's regulations provide that those States have ''30 days after the date of promulgation of the Federal standard to adopt a State emergency temporary standard,'' or to demonstrate ''that promulgation of an emergency temporary standard is not necessary because the State standard is already the same or at least as effective as the Federal standard change.'' 29 CFR 1953.5(b)(1). The new ETS becomes part of the OSHA-approved State Plan through the State Plan's submission to OSHA documentation showing it adopted an identical ETS or a ''Plan Change Supplement'' showing that it has adopted requirements that are ''at least as effective'' as federal OSHA's ETS. 29 CFR 1953.5(b)(3); 1953.4.

Even in States with OSHA-approved State Plans, any State law relating to an occupational safety and health issue that OSHA regulates is preempted unless it is submitted for OSHA's approval as a supplement to the State Plan. *Indust. Truck Ass'n*, 125 F.3d at 1311 (''If a State wishes to regulate an issue of worker safety for which a federal standard is in effect, its only option is to obtain the prior approval of the Secretary of Labor . . . [and] [i]t would make the state plan approval requirement superfluous if a state could pick and choose which occupational health and safety regulations to submit to OSHA''). Thus, a State or local requirement banning or limiting employer vaccine mandates would similarly be preempted because it has not been approved by federal OSHA as part of the State Plan. And, indeed, it could not be approved by federal OSHA, because such bans or limitations undercut the ETS's requirements and are clearly not as effective as the federal ETS. See 29 U.S.C. 667(c)(2).[86]

Finally, this provision includes a note that this section establishes minimum requirements for employers, that nothing in this section prevents employers from agreeing with their employees to implement additional measures, and that this section does not supplant collective bargaining agreements or other collectively negotiated agreements in effect that may have negotiated terms that exceed the requirements herein. It also references the National Labor Relations Act of 1935, which protects most private-sector employees' right to take collective action. The purpose of this note is to remind employers and employees that OSHA's ETS establishes a floor for protections, and that it does not preclude bargaining for additional protective measures. For example, employers might agree to cover the costs of face coverings or medical removal, or to a requirement that all employees, regardless of vaccination status, wear face coverings while working indoors.

[84] In addition, some State and local governments have adopted vaccination mandates directed at State and/or local government employees. The OSH Act and OSHA's standards would not preempt such requirements since State or local government employers and employees are exempt from OSHA coverage under the OSH Act. 29 U.S.C. 652 (5) (defining employer to exclude ''any State or political subdivision of a State''). However, many State and local government employers in States with OSHA-approved State Plans will be covered by State occupational safety and health requirements, and State Plans must adopt requirements for State and local government employers, as well as covered private sector employers, that are at least as effective as federal OSHA's requirements; State Plans may also choose to adopt more protective occupational safety and health requirements. 29 U.S.C. 667(c).

[85] As previously discussed, bans on mandating vaccinations or face coverings have not typically been generally applicable, but even the least workplace-specific, most generally applied bans will not survive preemption because they directly interfere with the ETS's regulatory scheme.

[86] For example, Arizona has an OSHA-approved State Plan, but its vaccination ban, which is not part of its State Plan, is preempted by this ETS (see AZ Executive Order 2021–18, Aug. 16, 2021).

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B. Scope and Application

Paragraph (b)(1) of this ETS provides that the ETS applies to all employers that have a total of at least 100 employees at any time the ETS is in effect. OSHA has determined that the unvaccinated employees of these employers face a grave danger of exposure to SARS–CoV–2, including the Delta variant, while they are at work (see *Grave Danger*, Section III.A. of this preamble). Because this grave danger finding applies to all unvaccinated employees who come into contact with other people in indoor work settings as part of their employment, this ETS is not limited by industrial sector or NAICS code. Therefore, this standard generally covers employers in all workplaces that are under OSHA's authority and jurisdiction, including industries as diverse as manufacturing, retail, delivery services, warehouses, meatpacking, agriculture, construction, logging, maritime, and healthcare.

I. Decision To Limit Coverage of This ETS to Employers With 100 or More Employees

This ETS applies to employers with a total of 100 or more employees at any time the standard is in effect. In light of the unique occupational safety and health dangers presented by COVID–19, and against the backdrop of the uncertain economic environment of a pandemic, OSHA established this coverage threshold for four reasons. First, OSHA is confident that employers with 100 or more employees will be able to meet the standard's requirements promptly, as the emergency addressed by the standard necessitates. OSHA is less confident that smaller employers can do so without undue disruption. Second, this coverage threshold will enable the standard to reach two-thirds of all private-sector workers in the nation, providing them with prompt protection. Third, the standard will reach the largest facilities, where the most deadly outbreaks of COVID–19 can occur. Fourth, the 100-employee threshold in this standard is comparable with the size thresholds established by congressional and agency decisions in analogous contexts.

a. Challenges to Feasibility Analysis for Small Businesses

An OSHA standard, including an ETS, must be both economically and technologically feasible. A standard is economically feasible under the OSH Act if it neither threatens ''massive dislocation to'' nor upsets the ''competitive stability of'' the regulated industries. *United Steelworkers of Am., AFL–CIO–CLC* v. *Marshall*, 647 F.2d 1189, 1265 (D.C. Cir. 1980). Technological feasibility has been interpreted broadly to mean ''capable of being done'' *Am. Textile Mfrs. Inst.* v. *Donovan*, 452 U.S. 490, 509–510 (1981).

As shown in *Economic Analysis*, Section IV.B. of this preamble, OSHA is confident that this standard is feasible for employers with 100 or more employees. OSHA is not at this time making any determination about whether it would be appropriate to extend the ETS to cover smaller employers. Put simply, the agency is requiring that employers it is confident can implement the provisions of the standard without delay do so. At the same time, the agency is soliciting public comment and seeking additional information to assess the ability of smaller employers to do so in the rulemaking commenced by this ETS. OSHA will determine the issue on the basis of the record, after receiving public comment.[87] The SARS–CoV–2 virus continues to spread rapidly, and each day that passes, tens of thousands more people are infected. The employees of larger firms should not have to wait for the protections of this standard while OSHA takes the additional time necessary to assess the feasibility of the standard for smaller employers.

The pandemic has presented special challenges for small businesses. According to a survey conducted during its early stages, 66% of businesses with fewer than 100 employees had suffered revenues losses exceeding 30%. (SHRM, May 6, 2020a). By contrast, only 27% of larger businesses with more than 100 employees had seen revenue drops of more than 30% (SHRM, May 6, 2020b). More recently, 61% of the members of the National Federation of Independent Businesses, mostly very small businesses, responded to a survey reported that they were experiencing staff shortages, with half of that group reporting a moderate to significant loss of sales because of unfilled positions (NFIB, July 12, 2021).

The requirements of the ETS could have a differential impact on small businesses compared with larger firms. Many small businesses lack separate human resources departments and struggle to carry out HR functions. A study found that some 70% of small businesses (with 5 to 49 employees) handle HR tasks in an ad hoc way. (ADP, December 2016). Only 23% of ad hoc managers believed they had the tools and resources necessary to perform HR tasks well, and only 19% were fully confident in their ability to handle HR tasks without making mistakes (ADP, December 2016). Another survey found that HR functions are proportionally far more expensive for smaller firms than for larger (small firms defined as up to 250 workers) (SHRM, 2015). The ETS requires employers to establish new systems to track vaccination status among workers, to keep related records, and for firms that allow the testing option, to keep records of each test.

[87] If OSHA receives information suggesting that a broader scope would be appropriate, the agency could expand the scope of the ETS quickly through a supplemental action. *Fla. Peach Growers Ass'n, Inc.* v. *U. S. Dep't of Labor*, 489 F.2d 120, 127 (5th Cir. 1974) (''It is inconceivable that Congress, having granted the Secretary the authority to react quickly in fast-breaking emergency situations, intended to limit his ability to react to developments subsequent to his initial response.'')

These records must be treated as confidential medical records subject to detailed regulations, which is not something most smaller employers typically need to do or have existing systems in place to address. 29 CFR 1910.1020. While OSHA has imposed similar requirements on smaller employers before, it has typically done so in highly regulated industries, such as healthcare, or in industries involving complicated industrial processes, which already require a certain degree of administrative capacity even when not responding to a grave danger, through a rulemaking process that provides additional time for notice and implementation, and when there is more time to assess the impact that the standard would have on small business. This emergency standard by contrast applies across the board to all industries, including less regulated retail and service sectors.

Moreover, OSHA estimates that some 5% of employees may have a medical contraindication or request an accommodation from the rule's requirements for disability or sincerely held religious belief reasons. (Please see *Economic Analysis*, Section IV.B. of this preamble). Assessing these requests may require more resources for smaller firms with less experience in this area, particularly if they lack HR staff. By the same token, a delay in applying the ETS to businesses with fewer than 100 employees would allow those businesses the benefit of learning from the models established by larger businesses with respect to accommodations. Similarly, implementing the ETS's testing provisions in a stepwise fashion will allow OSHA the time necessary to assess any impact the new requirements may have on the testing infrastructure and related supply chains before considering extending those requirements to additional employers.

b. The ETS Provides Prompt Protection for Most of America's Workforce

The 100 employee threshold means the ETS will reach two-thirds of the nation's private sector workforce, providing protection to millions of workers while issues regarding smaller firms are reviewed. OSHA considered that a 100 employee threshold was superior to a 150 employee threshold in this respect, because it would protect more employees: 67% rather than 63%, which is a difference of 4.856 million workers. (U.S. Census Bureau, May 2021). And while a 50 employee threshold would have covered more employees (78%), it would have required additional feasibility analysis, while still leaving many employees outside the standard. (U.S. Census Bureau, May 2021).

c. The ETS Will Help Prevent Large Outbreaks of COVID–19

The ETS's focus on employers with more than 100 employees will also help prevent large-scale outbreaks. As addressed in more detail in the discussion of *Grave Danger* (Section III.A. of this preamble), all unvaccinated employees who work in indoor settings face a grave danger from COVID–19, which is why the scope of the ETS is not limited to worksites of a specific size. The standard is based on employer size primarily because administrative capacity is more closely related to employer size. In addition, employer size provides a clear measure that is easy for employers (and OSHA) to track, as opposed to an alternative such as a workplace-based approach, which could fluctuate from day to day and mean more places and information for the employer to track. But OSHA also chose the 100 employee size threshold in recognition of the fact that larger employers are more likely to have many employees gathered in the same location. For employers with 100 or more employees, the median number of employees at any one location is approximately 50 (the average is also 50). (U.S. Census Bureau, May 2021). For employers with fewer than 100 employees, the median number of any one location is approximately 2 (with an average number of 7) (U.S. Census Bureau, May 2021).

Employees at larger locations are statistically more likely to be exposed to someone with COVID–19 during the course of their shifts, and thus face a heightened risk of virus transmission. Studies indicate that introduction of infection and the risk of infection transmission is increased with the size of a gathering (Champredon et al., April, 2021), and with larger populations (Shacham et al., July 5, 2021). See also (Contreras et al., July, 2021) (concluding that outbreaks were larger and lasted longer at facilities with more onsite staff). It is therefore not surprising that significant COVID–19 outbreaks have occurred at large facilities of employers with 100 or more employees [88] (Oregon Health Authority, October 6, 2021; CDPHE, October 6, 2021). A study of outbreaks in Los Angeles County found that the median number of employees in an establishment in which an outbreak occurred was 95, well above the 50 employee median for locations of employers covered by this rule, indicating that the rule will protect employees in the places where outbreaks are most likely to occur. (Contreras et al., July, 2021). And those outbreaks occurred even before the emergence of the SARS–CoV–2 Delta variant, which the CDC says ''causes more infections and spreads faster than early forms of SARS–CoV–2.'' (CDC, August 26, 2021) In fact, the studies noted earlier in this paragraph were published just as the Delta variant was emerging, meaning that the risk of transmission cited in those studies has likely increased.

While virus transmission is certainly not limited to large facilities, the potential scope of an outbreak is inherently more limited when fewer employees are present. In limiting the scope of the ETS to employers with 100 or more employees, OSHA is prioritizing coverage of those businesses in which the spread of the virus could potentially affect the largest number of employees and for which the agency is most confident that it is feasible to apply the standard.

d. Analogous Regulatory Regimes Use Comparable Employee Size Thresholds

Congress and federal agencies have frequently recognized that an employee size threshold may be appropriate in different regulatory contexts. They have not settled on any one number as the most appropriate, presumably because that depends on balancing different considerations that are relevant to the particular context, as OSHA has done here. But several analogous regulatory regimes use employee size thresholds comparable to the one selected here, in light of similar concerns about administrative feasibility.

For example, the EEOC has issued regulations requiring employers with 100 or more employees to submit annual reports related to equal employment opportunity in their workforce, in recognition that larger employers are better equipped to absorb the types of administrative burdens

[88] See, *e.g.,* Oregon Health Authority, October 6, 2021, (publishing data on outbreaks in large workplaces including two Amazon facilities, several hospitals, and a Walmart distribution center); CDPHE, Oct. 6, 2021, (identifying an active Covid outbreak in Cargill's Fort Morgan, CO meat processing plant, which employs more than 2,000 workers). While some have speculated that clusters of infections among employees at the same facility might result initially from shared exposures outside of work, the original source of the infection would have little bearing on the statistical probability of exposure and transmission once the infected people are together in the workplace with unvaccinated co-workers. The most effective way to prevent further transmission is to protect the other workers through vaccination or, when that is not possible, identify and remove the infected workers from the workplace as quickly as possible.

imposed by surveying, tracking and recordkeeping requirements. See 42 U.S.C. 2000e–8(c), 29 CFR 1602.7–.14 and 41 CFR 60–1.7(a). In earlier measures adopted in response to the COVID–19 pandemic, Congress adopted special protections and exemptions based on employee counts. The Families First Coronavirus Response Act, Public Law 116–127 (2020), sections 7001 and 7003 provided tax credits to businesses with fewer than 500 employees to assist compliance with the Act's expansion of paid sick and family leave, in recognition of the challenges facing smaller employers. Congress again relied on the same 500 employee threshold when it later extended tax credits only to employers who granted employees paid time off to be vaccinated, implicitly acknowledging the financial obstacles that can exist for smaller employers for the same activity that this ETS promotes (and without the vaccine policy and verification requirement in this ETS). American Rescue Plan Act, Public Law 117–2, Sec. 9641 (2021).

In the Affordable Care Act, Congress set the maximum size of a ''small employer'' at 100 employees for purposes of allowing greater flexibility to these employers. 42 U.S.C.A. 18024(b)(3). Likewise, private employers with fewer than 50 employees are exempt from complying with the Family and Medical Leave Act, in recognition of smaller employers' decreased administrative capacity, as well as their inability to easily accommodate employee absences. 29 U.S.C.A. 2611(2)(b)(2).

e. The 100 Employee Coverage Provision Is a Reasonable Exercise of the Secretary's Authority

OSHA's choice of a 100 employee threshold is based on balancing the fundamentally incommensurable considerations described above. Under the statute OSHA ''shall'' issue an ETS when employees are exposed to grave danger, and is not to follow normal notice and comment procedures to build a record. 29 U.S.C. 655(e). But OSHA may not issue an ETS unless it shows that the rule is feasible for the employers covered, and it has not yet made a feasibility determination for smaller employers. In the circumstances of this case, OSHA considered that an ETS was urgently needed to protect employees, that a 100 employee threshold would protect the great majority of them and prevent the largest outbreaks, that it would avoid the delays that would be needed if the agency were required to gather information and analyze feasibility for smaller employers, and that a comparable size threshold has been found appropriate in similar contexts. Where employees are dying every day, it is not unreasonable for the agency to prioritize doing what it can to address the problem quickly, regardless of whether there are further actions it might be able to take later.

Doing so implements the statutory delegation of authority to the agency to establish priorities for issuing standards by giving ''due regard to the urgency of the need'' for standards for particular workplaces. 29 U.S.C. 655(g). The courts have recognized that this provision authorizes the Secretary to make reasonable decisions limiting the scope of a standard, particularly where as here the agency has said it will address the reserved issue in subsequent rulemaking. *Forging Indus. Assoc.* v. *Donovan,* 773 F.2d 1436, 1454 (4th Cir. 1985) (hearing conservation standard); *United Steelworkers of Am.* v. *Marshall,* 647 F.2d 1189, 1309–1310 (D.C. Cir. 1980) (lead standard).

Where competing considerations are in play and there is no clear perfect choice, OSHA has a degree of discretion to draw a reasonable line. Courts have consistently recognized that agencies have discretion to draw reasonable lines. As the D.C. Circuit has explained: An agency has ''wide discretion'' in making line-drawing decisions and ''[t]he relevant question is whether the agency's numbers are within a zone of reasonableness, not whether its numbers are precisely right.'' *WorldCom, Inc.* v. *FCC,* 238 F.3d 449, 462 (D.C. Cir. 2001) (quotation marks omitted). An agency ''is not required to identify the optimal threshold with pinpoint precision. It is only required to identify the standard and explain its relationship to the underlying regulatory concerns.'' Id. at 461–62. *Nat'l Shooting Sports Found.* v. *Jones,* 716 F.3d. 200, 214–215 (D.C. Cir 2013). See also *Providence Yakima Med. Ctr.* v. *Sebelius*, 611 F.3d 1181, 1190–1191 (9th Cir. 2010).

For the reasons discussed above, the balance the agency struck here falls well within this zone of reasonableness.

II. Explanation of Who Is Included in the 100-Employee Threshold

The applicability of this ETS is based on the size of an employer, in terms of number of employees, rather than on the type or number of workplaces. In determining the number of employees, employers must include all employees across all of their U.S. locations, regardless of employees' vaccination status or where they perform their work. Part-time employees do count towards the company total, but independent contractors do not. As discussed above, OSHA has not found that the standard is feasible for firms with fewer than 100 employees, because it needs additional time to assess the impact of the standard on these employers, particularly as many smaller firms lack separate human resources departments and may face additional challenges when carrying out human resources functions. In contrast, OSHA has determined that the standard is feasible for firms with 100 or more employees, regardless of where those employees report to work. These firms generally have greater administrative capacities, and including all such employers in the scope of this ETS ensures that OSHA can cover two-thirds of all workers in the private sector as quickly as possible.

For a single corporate entity with multiple locations, all employees at all locations are counted for purposes of the 100-employee threshold for coverage under this ETS. In a traditional franchisor-franchisee relationship in which each franchise location is independently owned and operated, the franchisor and franchisees would be separate entities for coverage purposes, such that the franchisor would only count ''corporate'' employees, and each franchisee would only count employees of that individual franchise. In other situations, two or more related entities may be regarded as a single employer for OSH Act purposes if they handle safety matters as one company, in which case the employees of all entities making up the integrated single employer must be counted.

In scenarios in which employees of a staffing agency are placed at a host employer location, only the staffing agency would count these jointly employed workers for purposes of the 100-employee threshold for coverage under this ETS. Although the staffing agency and the host employer would normally share responsibility for these workers under the OSH Act, this ETS raises unique concerns in that OSHA has set the threshold for coverage based primarily on administrative capacity for purposes of protecting workers as quickly as possible, as discussed above, and the staffing agency would typically handle administrative matters for these workers. Thus, for purposes of the 100-employee threshold, only the staffing agency would *count* the jointly employed employees. The host employer, however, would still be covered by this ETS if it has 100 or more employees in addition to the employees of the staffing agency. For enforcement purposes, traditional joint employer principles would apply where both employers are covered by the ETS, as

illustrated further by the examples below. See also *https://www.osha.gov/temporaryworkers/.*

On a typical multi-employer worksite such as a construction site, *each* company represented—the host employer, the general contractor, and each subcontractor—would only need to count its *own* employees, and the host employer and general contractor would not need to count the total number of workers at each site. That said, each employer must count the total number of workers it employs regardless of where they report for work on a particular day. Thus, for example, if a general contractor has more than 100 employees spread out over multiple construction sites, that employer is covered under this ETS even if it does not have 100 or more employees present at any one worksite. Covering the employees of larger employers at multi-employer worksites would mitigate the spread of COVID–19 at the workplace even where not all employees are covered by this ETS because fully vaccinated employees (or unvaccinated employees wearing face coverings and submitting to weekly testing) would be less likely to spread the virus to unvaccinated workers at the site who are not covered by this ETS.

The determination as to whether a particular *employer* is covered by the standard should be made separately from whether individual *employees* are covered by the standard's requirements, as described by paragraph (b)(3) (*e.g.,* some employers may be covered but have no duties with respect to some of their employees under this standard). Some additional examples include:

- If an employer has 75 part-time employees and 25 full-time employees, the employer would be within the scope of this ETS because it has 100 employees.
- If an employer has 150 employees, 100 of whom work from their homes full-time and 50 of whom work in the office at least part of the time, the employer would be within the scope of this ETS because it has more than 100 employees.
- If an employer has 102 employees and only 3 ever report to an office location, that employer would be covered.
- If an employer has 150 employees, and 100 of them perform maintenance work in customers' homes, primarily working from their company vehicles (*i.e.,* mobile workplaces), and rarely or never report to the main office, that employer would also fall within the scope.
- If an employer has 200 employees, all of whom are vaccinated, that employer would be covered.
- If an employer has 125 employees, and 115 of them work exclusively outdoors, that employer would be covered.
- If a single corporation has 50 small locations (*e.g.,* kiosks, concession stands) with at least 100 total employees in its combined locations, that employer would be covered even if some of the locations have no more than one or two employees assigned to work there.
- If a host employer has 80 permanent employees and 30 temporary employees supplied by a staffing agency, the host employer would not count the staffing agency employees for coverage purposes and therefore would not be covered. (So long as the staffing agency has at least 100 employees, however, the staffing agency would be responsible for ensuring compliance with the ETS for the jointly employed workers.)
- If a host employer has 110 permanent employees and 10 temporary employees from a small staffing agency (with fewer than 100 employees of its own), the host employer is covered under this ETS and the staffing agency is not.
- If a host employer has 110 permanent employees and 10 employees from a large staffing agency (with more than 100 employees of its own), both the host employer and the staffing agency are covered under this standard, and traditional joint employer principles apply.
- Generally, in a traditional franchisor-franchisee relationship, if the franchisor has more than 100 employees but each individual franchisee has fewer than 100 employees, the franchisor would be covered by this ETS but the individual franchises would not be covered.

As explained earlier, part of OSHA's rationale in adopting the 100-employee threshold is to focus the ETS on companies that OSHA is confident will have sufficient administrative systems in place to comply quickly with the ETS. Thus, the ETS applies to all employers who have the requisite number of employees at any time this ETS is in effect. Along with employers that always have more than 100 employees, OSHA intends to cover employers that fluctuate above and below the 100-employee threshold during the term of the ETS because those employers will typically have already developed systems and capabilities for compliance; a decrease in the number of employees is therefore unlikely to make them less capable of compliance.

The determination of whether an employer falls within the scope of this ETS based on number of employees should initially be made as of the effective date of the standard, as set out in paragraph (m)(1). If the employer has 100 or more employees on the effective date, this ETS applies for the duration of the standard. If the employer has fewer than 100 employees on the effective date of the standard, the standard would not apply to that employer as of the effective date. However, if that same employer subsequently hires more workers and hits the 100-employee threshold for coverage, the employer would then be expected to come into compliance with the standard's requirements. Once an employer has come within the scope of the ETS, the standard continues to apply for the remainder of the time the standard is in effect, regardless of fluctuations in the size of the employer's workforce. For example, an employer that has 103 employees on the effective date of the standard, but then loses four within the next month, would continue to be covered by the ETS. OSHA is confident that employers with 100 or more employees at any point while this ETS is in effect have the administrative capacity to comply with the ETS, even if the number of employees fluctuates somewhat above and below 100.

Paragraph (b)(2) of this ETS sets forth two exemptions to the standard.[89] Under paragraph (b)(2)(i), this ETS does not apply to workplaces covered by the Safer Federal Workforce Task Force COVID–19 Workplace Safety: Guidance for Federal Contractors and Subcontractors (see Safer Federal Workforce Task Force, September 24, 2021). With limited exceptions, such as where a medical contraindication, disability, or sincerely held religious belief would prevent an employee from complying with certain provisions, those guidelines require covered

[89] Note that, in addition to the scope exceptions contained in the ETS itself, which are discussed in this section, there may be situations where the ETS does not apply by operation of the OSH Act. For example, the OSH Act does not apply to working conditions of employees with respect to which other Federal agencies have exercised their statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health (see 29 U.S.C. 653(b)(1)). Moreover, the ETS does not apply where states with OSHA-approved occupational safety and health programs (''State Plans'') have coverage (see 29 U.S.C. 667). State Plans must adopt and enforce COVID–19 requirements that are at least as effective as this ETS. Finally, the ETS does not apply to state and local government employers in states without State Plans (see 29 U.S.C. 652(5)).

contractors to ensure that all covered contractor employees (1) are fully vaccinated by December 8, 2021; (2) follow CDC guidelines for masks and physical distancing, including masking and distancing requirements based on the employee's vaccination status and the level of community transmission of COVID–19 where the workplace is located; and (3) designate a person to coordinate COVID–19 workplace safety efforts at covered workplaces. Because covered contractor employees are already covered by the protections in those guidelines, OSHA has determined that complying with this standard in addition to the federal contractor guidelines is not necessary to protect covered contractor employees from a grave danger posed by COVID–19. Although there may be some respects in which the OSHA standard is somewhat more protective, such as providing paid leave for vaccination, the federal contractor guidelines are somewhat more protective in other respects, such as requiring vaccination for everyone who does not have a right to an accommodation rather than allowing employees to submit to testing in lieu of vaccination. In essence, they are similar but slightly different schemes that provide roughly equivalent protection, and OSHA has determined that imposing a second set of similar protections on covered federal contractors by subjecting them to this ETS in addition to the federal contractor guidance is not necessary at this time to reduce a grave danger to covered contractor employees from COVID–19.

Under Executive Order 14043, every federal agency must implement a program requiring each of its federal employees to be vaccinated against COVID–19, except as required by law. 86 FR 50989. OSHA will regard a federal agency's compliance with this requirement, and the related Safer Federal Workforce Task Force guidance issued under section 4(e) of Executive Order 13991 and section 2 of Executive Order 14043 (including guidance on employer support in the form of paid time for vaccination and paid leave for post-vaccination recovery), as sufficient to meet its obligation to comply with this ETS under Section 19 of the OSH Act and Executive Order 12196. In essence, the federal government has chosen the mandatory vaccination option of this rule, and all federal employees are required to be fully vaccinated by the compliance date of this standard, except where entitled to a reasonable accommodation. The Safer Federal Workforce Task Force's guidelines for vaccination verification are consistent with the ETS's (see Safer Federal Workforce Task Force, October 11, 2021). Note, however, that under the OSH Act, the U.S. Postal Service is treated as a private employer, see 29 U.S.C. 652(5), and it is therefore required to comply with this ETS in the same manner as any other employer covered by the Act.

For similar reasons, paragraph (b)(2)(ii) provides that this ETS does not apply in settings where any employee provides healthcare services or healthcare support services while they are covered by the requirements of 29 CFR 1910.502. Section 1910.502 requires a multi-layered suite of protections for employees covered by its requirements, including patient screening and management, facemasks or respirators, other personal protective equipment (PPE), limiting exposure to aerosol-generating procedures, physical distancing, physical barriers, cleaning, disinfection, ventilation, health screening and medical management, access to vaccination, and medical removal protection. Section 1910.502 was carefully tailored to the healthcare workplaces it covers and, given the full suite of protections it requires, including (like this ETS) the provision of paid time for vaccination, OSHA has determined that it adequately protects the employees covered by its requirements from the grave danger posed by COVID–19. Therefore, complying with the additional requirements of this ETS is not necessary to protect those employees while they are covered by that standard's protections.

OSHA's intent was to leave no coverage gaps between section 1910.502 and this ETS. In other words, the purpose of paragraph (b)(2)(ii) is to ensure that all workers in healthcare and healthcare support jobs who are at grave danger from exposure to SARS-CoV–2 are protected by either section 1910.502 or this ETS while performing their jobs. Therefore, it will be necessary for employers with employees covered by section 1910.502 to determine if they also have employees covered by this ETS. For example, a healthcare employer with more than 100 employees that has non-hospital ambulatory care facilities that are exempt under section 1910.502(a)(2)(iii) (for non-hospital ambulatory care settings where all non-employees are screened prior to entry and those with suspected or confirmed COVID–19 are prohibited from entry) would be required to protect the employees in those ambulatory care facilities under this ETS. Similarly, a retail pharmacy chain that operates a series of ambulatory care clinics embedded in its stores, where those embedded clinics are the only areas in the store that are covered under 1910.502 (see section 1910.502(a)(3)(i)), would have to ensure that the remainder of its employees in other parts of its stores are protected under this ETS if the company has 100 or more employees company-wide, including those covered under 1910.502.

Paragraph (b)(3) provides that, even where the standard applies to a particular employer, its requirements do not apply to employees: (i) Who do not report to a workplace where other individuals such as coworkers or customers are present; (ii) while working from home; or (iii) who work exclusively outdoors. OSHA intends these provisions to exempt workplace settings where workers do not interact indoors with other individuals, and to exempt work performed in the employee's home regardless of whether other individuals may be present in the home.

OSHA has determined that the provisions of this ETS are not necessary to protect employees from COVID–19 when they are working alone, or when they are working from home (see *Grave Danger,* Section III.A. of this preamble). These two provisions may overlap in some cases, but also can apply to slightly different situations. Paragraph (b)(3)(i) would apply to work in a solitary location, such as a research station where only one person (the employee) is present at a time. In that situation, the employee is not exposed to any potentially infectious individuals at work. Paragraph (b)(3)(ii) would apply to employees working in their homes, regardless of whether other individuals who are not employees of the same employer are present. In a home telework environment, many factors—such as the presence of family members and other individuals unrelated to the employee's work, who may not be fully vaccinated or wearing face coverings—may be beyond the employer's control. Employees are typically in the best position to manage COVID–19 risks in their homes. Note that the exemption in paragraph (b)(3)(ii) only applies to employees while they are working from home. An employee who switches back and forth from teleworking to working in a setting where other people are present (*e.g.,* an office) is covered by this ETS and must be vaccinated if required by the employer. If the employer does not require vaccination, the teleworking employee must either be vaccinated or complete testing and wear a face covering in accordance with their

employer's policy under paragraph (d). How often such an employee must be tested for COVID–19 and wear a face covering, however, depends on how often they report to the office (see, *e.g.,* paragraph (g)(1)(ii)).

Paragraph (b)(3)(iii) provides that, even if a particular employer is covered by the standard, the requirements of the standard do not apply to employees who work exclusively outdoors. OSHA has determined that COVID–19 does not pose a grave danger to employees who work exclusively outdoors because of the significantly reduced likelihood of transmission in outdoor settings. As discussed in more detail in Grave Danger (Section III.A. of this preamble), the record contains very little evidence of COVID–19 transmission in outdoor settings. And, in studies where clusters were identified in worksites characterized as being outdoors, the study authors were not able to identify specific incidents that led to transmission. In addition, workplaces characterized as ''outdoors'' may in fact involve significant time spent indoors. For example, on a construction site, workers inside a partially complete structure are not truly outdoors, and some individuals on a construction site may spend significant amounts of time in a construction trailer where other individuals are present. Workers at outdoor locations may also routinely share work vehicles. These indoor exposures could account for COVID–19 clusters among employees at worksites otherwise characterized as being outdoors. And employees whose outdoor time is interrupted by the indoor periods will still be subject to the requirements in this ETS.

Studies of athletic teams further indicate that evidence of COVID–19 clusters among workers characterized as working outdoors could actually be caused by indoor exposures. Even where athletes were in very close contact during outdoor exposures on the playing field, the study authors could not identify a single case of COVID–19 transmission between teams that occurred outdoors (see Mack *et al.,* January 29, 2021; Egger *et al.,* March 18, 2021; Jones *et al.,* February 11, 2021). For all of these reasons, and as discussed more fully in Grave Danger (Section III.A. of this preamble), OSHA has determined that COVID–19 does not pose a grave danger to employees who work exclusively outdoors.

As a practical matter, determining the applicability of paragraph (b)(3)(iii) depends on the working conditions of individual employees. For example, if a landscaping contractor has at least 100 employees and is not covered by the exemptions in paragraph (b)(2), the standard applies to that employer even if a majority of the company's employees work exclusively outdoors. The standard's protections would only apply to employees working in indoor settings around other individuals (other than telework in their own homes), not to those employees working exclusively outdoors. In some cases, it may be true that the standard applies to an employer but the employer would not have to implement its provisions at all because all of its employees fall within exemptions in paragraph (b)(3). Going back to the example of the large landscaping contractor, if all indoor workers either work from home or in locations where no other individuals are present, and all outdoors workers work exclusively outdoors and do not drive to worksites together in a company vehicle, the employer would be covered by the ETS but not required to comply with its provisions.

An employee will only be covered by the exemption in paragraph (b)(3)(iii) if the employee works exclusively outdoors. Thus, an employee who works indoors on some days and outdoors on other days would not be exempt from the requirements of this ETS. Likewise, if an employee works primarily outdoors but routinely occupies vehicles with other employees as part of work duties, that employee is not covered by the exemption in paragraph (b)(3)(iii). However, if an employee works outdoors for the duration of every workday except for de minimis use of indoor spaces where other individuals may be present—such as a multi-stall bathroom or an administrative office—that employee would be considered to work exclusively outdoors and covered by the exemption under paragraph (b)(3)(iii) as long as time spent indoors is brief, or occurs exclusively in the employee's home (*e.g.,* a lunch break at home). Extremely brief periods of indoor work would not normally expose employees to a high risk of contracting COVID–19; however, OSHA will look at cumulative time spent indoors to determine whether that time is de minimis. Thus, if there are several brief periods in a day when an employee goes inside, OSHA will total those periods of time when determining whether the exception for exclusively outdoors work applies.

Finally, to qualify for this exception, the employee's work must truly occur ''outdoors,'' which would not include buildings under construction where substantial portions of the structure are in place, such as walls and ceiling elements that would impede the natural flow of fresh air at the worksite. Workplaces that are truly outdoors typically do not include any of the characteristics that normally enable transmission of SARS–CoV–2 to occur, such as poor ventilation, enclosed spaces, and crowding. As discussed in Bulfone et al. (November 29, 2020), the lower risk of transmission in outdoor settings (*i.e.,* open air or structures with only one wall) is likely due to increased ventilation with fresh air and a greater ability to maintain physical distancing (see *Grave Danger,* Section III.A. of this preamble, for more information on risk of transmission outdoors).

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C. Definitions

Paragraph (c) of the ETS provides definitions of terms used in the section.

''Assistant Secretary'' means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee. This definition provides clarification about who can request and receive records specified in paragraph (l)(3) of this section. A designee includes a representative conducting an inspection or an investigation.

''COVID–19 (Coronavirus Disease 2019)'' means the disease caused by SARS–CoV–2 (severe acute respiratory syndrome coronavirus 2). SARS–CoV–2 is a highly transmissible virus that spreads primarily through the respiratory droplets that are produced when an infected person coughs, sneezes, sings, talks, or breathes. The nature of the disease, variants of SARS–CoV–2, disease transmission, and associated health effects are all described in great detail in Grave Danger (Section III.A. of this preamble). For clarity and ease of reference, the ETS also uses the term ''COVID–19'' when describing exposures or potential exposures to SARS–CoV–2. The requirements of the ETS are intended to address the grave danger of exposure to COVID–19 in the workplace.

A ''COVID–19 test'' means a test for SARS–CoV–2 that is: (1) Cleared, approved, or authorized, including in an Emergency Use Authorization (EUA), by the U.S. Food and Drug Administration (FDA) to detect current infection with the SARS–CoV–2 virus (*e.g.,* a viral test); (2) administered in accordance with the authorized instructions; and (3) not both self-administered and self-read unless observed by the employer or an authorized telehealth proctor. Examples of tests that satisfy this requirement include tests with specimens that are processed by a laboratory (including home or on-site collected specimens which are processed either individually or as pooled specimens), proctored over-the-counter tests, point of care tests, and tests where specimen collection and processing is either done or observed by an employer.

Under paragraph (g), employees who are not fully vaccinated must be tested for COVID–19. When an employee must be tested, the test is considered acceptable only if the test and the administration of the test satisfy the definition of COVID–19 test in this standard.

COVID–19 tests can broadly be divided into two categories, diagnostic tests and antibody tests. Diagnostic tests detect parts of the SARS–CoV–2 virus and can be used to diagnose current infection. On the other hand, antibody tests look for antibodies in the immune system produced in response to SARS–CoV–2, and are not used to diagnose an active COVID–19 infection. Antibody tests do not meet the definition of COVID–19 test for the purposes of this ETS.

Diagnostic tests for current infection fall into two categories: Nucleic acid amplification tests (NAATs) and antigen tests. NAATs are a type of molecular test that detect genetic material (nucleic acids); NAATs for COVID–19 identify the ribonucleic acid (RNA) sequences that comprise the genetic material of the virus. NAATs can reliably detect small amounts of SARS–CoV–2 and are unlikely to return a false-negative result. NAATs use many different methods to detect the virus, including reverse transcription-polymerase chain reaction (RT–PCR), which is a high-sensitivity, high-specificity [90] test for diagnosing SARS–CoV–2 infection. Other types of NAATs that use isothermal amplification methods include nicking endonuclease amplification reaction (NEAR), transcription mediated amplification (TMA), loop-mediated isothermal amplification (LAMP), helicase-dependent amplification (HDA), clustered regularly interspaced short palindromic repeats (CRISPR), and strand displacement amplification (SDA) (CDC, June 14, 2021).

Most NAATs need to be processed in a laboratory with variable time to receive results (approximately 1–2 days), but some NAATs are point-of-care tests with results available in about 15–45 minutes. As of October 14, 2021, 264 molecular tests (NAATs) and collection devices have EUA from the FDA for COVID–19 (FDA, October 14, 2021b). These tests may be acceptable under the ETS.

Antigen tests may also meet the definition of COVID–19 test under this standard. Antigen tests indicate current infection by detecting the presence of a specific viral antigen. Most can be processed at the point of care with results available in about 1530 minutes. Antigen tests generally have similar specificity to, but are less sensitive than, NAATs (CDC, October 7, 2021). As of October 14, 2021, thirty-seven antigen

[90] Test sensitivity indicates the ability of a test to correctly identify people who have a disease. Test specificity indicates the ability of a test to correctly identify people who do not have a disease. A test with high sensitivity and high specificity minimizes inaccurate results.

tests have EUA from the FDA for COVID–19 (FDA, October 14, 2021a). These tests may be acceptable under the ETS.

Most antigen tests and some NAATs are conducted at the point of care, which means the test processing and result reading is performed at or near the place where a specimen is collected so that results can be obtained within minutes rather than hours or days. Rapid point-of-care tests are administered in various settings operating under a Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate of waiver, such as physician offices, urgent care facilities, pharmacies, school health clinics, workplace health clinics, long-term care facilities and nursing homes, and at temporary locations, such as drive-through sites managed by local health organizations (FDA, November 16, 2020).

To be a valid COVID–19 test under this standard, a test may not be both self-administered and self-read unless observed by the employer or an authorized telehealth proctor. OSHA included the requirement for some type of independent confirmation of the test result in order to ensure the integrity of the result given the ''many social and financial pressures for test-takers to misrepresent their results'' (Schulte *et al.,* May 19, 2021). This independent confirmation can be accomplished in multiple ways, including through the involvement of a licensed healthcare provider or a point-of-care test provider. If an over-the-counter (OTC) test is being used, it must be used in accordance with the authorized instructions. The employer can validate the test through the use of a proctored test that is supervised by an authorized telehealth provider. Alternatively, the employer could proctor the OTC test itself.

Employers have the flexibility to select the testing scenario that is most appropriate for their workplace. Some employees and employers may rely on testing that is conducted by a healthcare provider (*e.g.,* doctor or nurse) who arranges for the specimen to be analyzed at a laboratory or at a point-of-care testing location (*e.g.,* a pharmacy). The involvement of licensed or accredited healthcare providers allows employers to have a high degree of confidence in the suitability of the test and the test results. Some large employers who set up their own on-site testing program may partner with a healthcare organization (*e.g.,* a local hospital or clinic) or rely on a licensed healthcare provider to help obtain a CLIA certificate of waiver. Other employers may simply require that employees perform and read their own OTC test while an authorized employee observes the administration and reading of the test to ensure that a new test kit was used and that the test was administered properly (*e.g.,* nostrils were swabbed), and to witness the test result.

Due to the potential for employee misconduct (*e.g.,* falsified results), tests that are both self-administered and self-read are not acceptable unless they are observed by the employer or an authorized telehealth proctor. Some COVID–19 tests are authorized by the FDA to be performed only with the supervision of a telehealth proctor, which is someone who is trained to observe sample collection and provide instructions and result interpretation assistance to individuals using the test. The term ''authorized telehealth proctor'' refers to proctors who follow the requirements for proctoring specified by the FDA authorization. For a more detailed discussion on COVID–19 testing requirements under this ETS, see the Summary and Explanation for paragraph (g) (Section VI.G. of this preamble).

A ''face covering'' means a covering that: (1) Completely covers the nose and mouth; (2) is made with two or more layers of a breathable fabric that is tightly woven (i.e., fabrics that do not let light pass through when held up to a light source); (3) is secured to the head with ties, ear loops, or elastic bands that go behind the head. If gaiters are worn, they should have two layers of fabric or be folded to make two layers; (4) fits snugly over the nose, mouth, and chin with no large gaps on the outside of the face; and (5) is a solid piece of material without slits, exhalation valves, visible holes, punctures, or other openings. This definition includes clear face coverings or cloth face coverings with a clear plastic panel that, despite the non-cloth material allowing light to pass through, otherwise meet this definition and which may be used to facilitate communication with people who are deaf or hard-of-hearing or others who need to see a speaker's mouth or facial expressions to understand speech or sign language respectively. Face coverings can be manufactured or homemade, and they can incorporate a variety of designs, structures, and materials. Face coverings provide variable levels of protection based on their design and construction.

As explained in paragraph (i), face covering use is required based on an employee's vaccination status. The criteria in the definition help to ensure that face coverings that are worn by workers who are not fully vaccinated will provide effective source control and some degree of personal protection. Source control means reducing the spread of large respiratory droplets to others by covering a person's mouth and nose. The personal protection afforded by face coverings, as well as the benefits and necessity, are described in the Summary and Explanation for paragraph (i) (Section VI.I. of this preamble).

Face coverings differ from facemasks and respirators, which are also defined in paragraph (c) of this section. Face coverings, unlike facemasks and respirators, are not considered to be personal protective equipment (PPE) under OSHA's general PPE standard (29 CFR 1910.132), as discussed in the *Summary and Explanation* for paragraph (i) (Section VI.I. of this preamble).

Lastly, face coverings as required by this standard do not have to meet a consensus standard, although face coverings that adhere to such consensus standards, with design and construction specifications, meet the definition and may offer both greater protection and the confidence that at least a minimum level of protection has been provided. The National Institute for Occupational Safety and Health (NIOSH) recommends that employers and workers who want a face covering that provides a known level of protection use face coverings that meet a new standard, called Workplace Performance and Workplace Performance Plus masks, for workplaces. As discussed in the *Summary and Explanation* for paragraph (i) (Section VI.I. of this preamble), the new NIOSH criteria and the ASTM Specification for Barrier Face Coverings, F3502–21 (ASTM Standard) provide a greater level of source control performance for workers when wearing the face covering according to manufacturer's instructions. The NIOSH criteria require that face coverings conform to the ASTM Standard and meet additional quantitative leakage criteria. Although not required by the standard, OSHA notes that face coverings that meet ASTM F3502–21 requirements and the new NIOSH criteria may offer a higher level of source control and wearer protection than those face coverings that do not meet a consensus standard.

A ''facemask'' means a surgical, medical procedure, dental, or isolation mask that is FDA-cleared, authorized by an FDA EUA, or offered or distributed as described in an FDA enforcement policy. Facemasks may also be referred to as ''medical procedure masks.'' This definition provides clarification about the exception to the face covering

requirement under paragraph (i)(1)(iii) that permits facemask use in lieu of face coverings. OSHA notes that facemasks are not respirators, which are also defined in this section.

Facemasks provide protection against exposure to splashes, sprays, and spatter of body fluids. Facemasks offer both source control, as defined in this section under face coverings, and protection for the wearer. OSHA has previously established that facemasks are essential PPE for employees in healthcare, under both the general PPE standard (29 CFR part 1910.132) and the Bloodborne Pathogens standard (29 CFR part 1910.1030). Although not required, the *Summary and Explanation* for paragraph (i) (Section VI.I. of this preamble) addresses their inclusion in this standard. Additional information on such facemasks can be found in relevant FDA guidance.

''Fully vaccinated'' means (i) a person's status 2 weeks after completing primary vaccination with a COVID–19 vaccine with, if applicable, at least the minimum recommended interval between doses in accordance with the approval, authorization, or listing that is: (A) Approved or authorized for emergency use by the FDA; (B) listed for emergency use by the World Health Organization (WHO); or (C) administered as part of a clinical trial at U.S. site, if the recipient is documented to have of primary vaccination with the ''active'' (not placebo) COVID–19 vaccine candidate, for which vaccine efficacy has been independently confirmed (*e.g.*, by a data and safety monitoring board) or if the clinical trial participant from the U.S. sites had received a COVID–19 vaccine that is neither approved nor authorized for use by the FDA but is listed for emergency use by the WHO. Currently-authorized FDA vaccines include Janssen (Johnson & Johnson), which is a single-dose primary vaccination, and Pfizer-BioNTech and Moderna, which have a two-dose primary vaccination series. This definition is consistent with the CDC definition of fully vaccinated (CDC, September 16, 2021).

The definition of ''fully vaccinated'' also means a person's status 2 weeks after receiving the second dose of any combination of two doses of a COVID–19 vaccine that is approved or authorized by the FDA, or listed as a two-dose series by the WHO (*i.e.,* heterologous primary series of such vaccines, receiving doses of different COVID–19 vaccines as part of one primary series). The second dose of the series must not be received earlier than 17 days (21 days with a 4-day grace period) after the first dose (CDC, October 15, 2021). OSHA has included this because people who have received a heterologous primary vaccination series (including mixing of mRNA, adenoviral, and mRNA plus adenoviral products) are considered by the CDC to also meet this definition. OSHA considers a vaccination series that meets the definition in subparagraph (ii) to be a primary vaccination for purposes of the requirements to support vaccination in paragraph (f).

The employer obligations under the ETS differ based on whether each employee is fully vaccinated. This definition is relevant to the definition of mandatory vaccination policy, in this paragraph (c), as well as the provisions under paragraph (d) regarding written vaccination policy requirements and relevant procedures for workers who are fully vaccinated. Paragraph (e)(2) also addresses fully vaccinated employees, including the determination of vaccination status and acceptable forms of proof. Lastly, the definition provides clarity with regard to the requirements of paragraphs (g) and (i) respectively, which contain requirements for regular COVID–19 testing and face covering use among employees who are not fully vaccinated.

Paragraph (e) requires employers to determine each employee's vaccination status, including whether they are fully or partially vaccinated. By ''partially vaccinated,'' OSHA means someone who has started a primary vaccination series but not completed it (*e.g.,* has received one dose of a two-dose series) or has completed their primary vaccination and two weeks have not elapsed since the last dose of the primary vaccination.

A ''mandatory vaccination policy'' is an employer policy requiring each employee to be fully vaccinated. To meet the definition of a mandatory vaccination policy, the policy must require: Vaccination of all employees, including vaccination of all new employees as soon as practicable, other than those employees (1) for whom a vaccine is medically contraindicated, (2) for whom medical necessity requires a delay in vaccination,[91] or (3) who are legally entitled to a reasonable accommodation under federal civil rights laws because they have a disability or sincerely held religious beliefs, practices, or observances that conflict with the vaccination requirement. OSHA intends that ''employee,'' as used in this definition, includes only employees that are covered by this ETS and does not include employees who are excluded from coverage under paragraph (b)(3).

Paragraph (d)(1) of the standard requires an employer to establish, implement, and enforce a written mandatory vaccination policy that meets this definition. The benefits of vaccination, including the effectiveness of vaccination mandates, are discussed in *Grave Danger* (Section III.A. of this preamble) and *Need for the ETS* (Section III.B. of this preamble).

OSHA recognizes that vaccination policies may vary, as indicated in paragraph (d)(2). Any policy that permits the employee to choose between vaccination and COVID–19 testing and face covering use would not be considered a mandatory vaccination policy under paragraph (d)(1), although such policy is permissible under paragraph (d)(2). In some cases, employers may implement vaccination policies that differ by location or type of business operation and thus the application of paragraph (d)(2) might vary across an employer's workforce. This is discussed in greater detail in the *Summary and Explanation* for paragraph (d) (Section VI.D. of this preamble).

A ''respirator'' is a type of PPE that is certified by NIOSH under 42 CFR part 84 or is authorized under an EUA by the FDA. These specifications are intended to ensure some consistent level of testing, approval, and protection and to prevent the use of counterfeit respirators that will not offer adequate protection, which is important because respirators are intended to protect the wearer when directly exposed to hazards. Respirators protect against airborne hazards by removing specific air contaminants from the ambient (surrounding) air or by supplying breathable air from a safe source. Common types of respirators include filtering facepiece respirators (*e.g.,* N95), elastomeric respirators, and powered air-purifying respirators (PAPRs). Face coverings, facemasks, and face shields are not respirators.

As stated above, there are various types of respirators that would fall within this definition. A *filtering facepiece respirator* (FFR) is a negative-pressure particulate respirator with a non-replaceable filter as an integral part of the facepiece or with the entire facepiece composed of the non-replaceable filtering medium. N95 FFRs are the most common type of FFR and are the type of respirator most often used to control exposures to infections transmitted via the airborne route. When properly worn, N95 FFRs filter at least 95% of airborne particles. An

[91] As defined by CDC's informational document, Summary Document for Interim Clinical Considerations for Use of COVID–19 Vaccines Currently Authorized in the United States (CDC, September 29, 2021).

elastomeric respirator is a tight-fitting respirator with a facepiece that is made of synthetic or rubber material that permits it to be disinfected, cleaned, and reused according to the manufacturer's instructions. Elastomeric respirators are equipped with replaceable cartridges, canisters, or filters. Lastly, a *powered air-purifying respirator* (PAPR) is an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

This standard does not require the use of respirators. This definition is included because it relates to paragraph (i)(1)(iii), which exempts employees from wearing face coverings when they are wearing respirators or facemasks. In addition, paragraph (i)(4) requires employers to permit employees to wear a respirator instead of a face covering and permits employers to provide respirators to their employees, instead of face coverings. When respirators are used pursuant to paragraph (i)(4), the employer must also comply with § 1910.504, the Mini Respiratory Protection Program.

NIOSH has developed a set of regulations in 42 CFR part 84 for testing and certifying non-powered, air-purifying, particulate-filter respirators. To help address concerns about availability during the COVID–19 pandemic, the FDA has issued EUAs for certain PPE products, including respiratory protective devices such as respirators. For the purposes of this standard, respirators certified by NIOSH, under 42 CFR part 84 or authorized under an EUA by the FDA meet the definition. Additional information on such respirators can be found in relevant FDA and NIOSH guidance.

A ''workplace'' is a physical location (*e.g.*, fixed, mobile) where the employer's work or operations are performed. It does not include an employee's residence, even if the employee is teleworking from their residence. Examples of fixed locations include: Offices, retail establishments, co-working facilities, and factories or manufacturing facilities. A workplace includes the entire site (including outdoor and indoor areas, a structure or a group of structures) or an area within a site where work or any work-related activity occurs (*e.g.,* taking breaks, going to the restroom, eating, entering or exiting work). The workplace includes the entirety of any space associated with the site (*e.g.,* workstations, hallways, stairwells, breakrooms, bathrooms, elevators) and any other space that an employee might occupy in arriving, working, or leaving. Examples of employees who have mobile workplaces include maintenance and repair technicians who go to homes or businesses to provide repair services, or those who provide delivery services.

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D. Employer Policy on Vaccination

Vaccination is a vital tool to reduce the presence and severity of COVID–19 cases in the workplace, in communities, and in the nation as a whole. Despite the robust protection against COVID–19 that vaccination affords, millions of eligible individuals have not yet been vaccinated. Current efforts to increase the proportion of the U.S. population that is fully vaccinated against COVID–19 are critical to ending the COVID–19 pandemic (CDC, September 15, 2021). As described more fully in *Need for the ETS* (Section III.B. of this preamble), mandatory vaccination policies work. Therefore, OSHA has determined that requiring or strongly encouraging vaccination—the most effective and efficient control for reducing COVID–19—is key to ensuring the protection of workers against the grave danger of exposure to SARS–CoV–2 in the workplace (see *Grave Danger,* Section III.A. of this preamble). Therefore, this ETS requires employers to adopt mandatory vaccination policies for their workplaces, with an exception for employers that instead adopt a policy allowing employees to elect to undergo regular COVID–19 testing and wear a face covering at work in lieu of vaccination. In *Need for the ETS* (Section III.B of this preamble), OSHA explains its rationale for providing the exception.

Paragraph (d) of this ETS is a critical element in ensuring employees' protection, as it requires covered employers to develop, implement, and enforce written policies on COVID–19 vaccination for their workforces. Paragraph (d)(1) requires the employer to establish, implement, and enforce a written mandatory vaccination policy. As defined in paragraph (c), a *mandatory vaccination policy* is an employer policy requiring each employee to be fully vaccinated. Such a policy must require vaccination of all employees, other than those employees who fall into one of three categories: (1) Those for whom a vaccine is medically contraindicated, (2) those for whom medical necessity requires a delay in

vaccination, or (3) those who are legally entitled to a reasonable accommodation under federal civil rights laws because they have a disability or sincerely held religious beliefs, practices, or observances that conflict with the vaccination requirement. The policy must also require all new employees to be vaccinated as soon as practicable.

Paragraph (d)(2) is a limited exemption from the mandatory vaccination policy requirement. As discussed in *Need for the ETS* (Section III.B. of this preamble), vaccination mandates are effective at increasing overall vaccination rates and protecting employees and, therefore, the agency encourages all employers to implement a mandatory vaccination policy. Under paragraph (d)(2), however, employers can avoid the mandate in paragraph (d)(1) if the employer establishes, implements, and enforces a written policy allowing any employee not subject to a mandatory vaccination policy to choose either to: (1) Be fully vaccinated against COVID–19 or (2) provide proof of regular testing for COVID–19 in accordance with paragraph (g) of this section and wear a face covering in accordance with paragraph (i). An employer who chooses to operate under paragraph (d)(2), however, must still offer the support for vaccination required under paragraph (f) and may not prevent employees from getting vaccinated. Adopting a policy under paragraph (d)(2) simply means that employees themselves may choose not to get vaccinated, in which case they must get tested and wear face coverings per the requirements of the standard.

OSHA recognizes there may be employers who develop and implement partial mandatory vaccination policies, *i.e.,* that apply to only a portion of their workforce. An example might be a retail corporation employer who has a mixture of staff working at the corporate headquarters, performing intermittent telework from home, and working in stores serving customers. In this type of situation, the employer may choose to require vaccination of only some subset of its employees (*e.g.,* those working in stores), and to treat vaccination as optional for others (*e.g.,* those who work from headquarters or who perform intermittent telework). This approach would comply with the standard so long as the employer complies in full with paragraph (d)(1) and (d)(2) for the respective groups.

OSHA uses the terms establish, implement, and enforce in paragraph (d) to emphasize that it is necessary for an employer to first determine its policy and create a written record of that policy. After determining the policy, an employer must then ensure that it is following the policy, as laid out in its written plan. Finally, employers must ensure that they enforce the requirements of their policies with respect to their workforce, through training and the use of such mechanisms as work rules and the workplace disciplinary system, if necessary. These requirements apply to the written policy required under paragraph (d), whether employers choose to implement the mandatory vaccination policy under paragraph (d)(1) or utilize the exemption under paragraph (d)(2) for all or a portion of their workforce.

To ensure that employers' vaccination policies under paragraph (d) are comprehensive and effective, the policies should address all of the applicable requirements in paragraphs (e)–(j) of this standard, including: Requirements for COVID–19 vaccination; applicable exclusions from the written policy (*e.g.,* medical contraindications, medical necessity requiring delay in vaccination, or reasonable accommodations for workers with disabilities or sincerely held religious beliefs); information on determining an employee's vaccination status and how this information will be collected (as described in paragraph (e)); paid time and sick leave for vaccination purposes (as described in paragraph (f)); notification of positive COVID–19 tests and removal of COVID–19 positive employees from the workplace (as described in paragraph (h)); information to be provided to employees (pursuant to paragraph (j)—*e.g.,* how the employer is making that information available to employees); and disciplinary action for employees who do not abide by the policy. In addition to addressing the requirements of paragraphs (e)–(j) of this standard, the employer should include all relevant information regarding the policy's effective date, who the policy applies to, deadlines (*e.g.,* for submitting vaccination information, for getting vaccinated), and procedures for compliance and enforcement, all of which are necessary components of an effective plan. Having a comprehensive written policy will provide a solid foundation for an effective COVID–19 vaccination program, while making it easier for employers to inform employees about the program-related policies and procedures, as required under paragraph (j)(1).

If an employer utilizes the exemption under paragraph (d)(2), its workplace may contain employees who are vaccinated and unvaccinated. This might be the case even for employers who establish a mandatory vaccination policy under paragraph (d)(1); for example, an employer with a mandatory vaccination policy might have employees who cannot be vaccinated for medical reasons. Given the additional safety protocols under this standard for individuals who are not fully vaccinated (see paragraphs (g) and (i)), an employer who has both vaccinated and unvaccinated employees will have to develop and include the relevant procedures for two sets of employees in the written policy. The procedures for those who are fully vaccinated should contain all the information previously discussed relevant to establishing, implementing, and enforcing a comprehensive written policy. However, the procedures applicable to employees who are not fully vaccinated (*i.e.,* those who decline vaccination, those who are unable to receive vaccination and are, absent undue hardship to their employers, entitled to reasonable accommodation) and those who are unable to provide proof of vaccination as required by paragraph (e) (who must be treated as not fully vaccinated), must include COVID–19 testing and face covering use as required by paragraphs (g) and (i), respectively, unless the reasonable accommodation from vaccination removes the employee from the scope of § 1910.501 (*e.g.,* full time telework consistent with one of the exceptions in § 1910.501(b)(3)). OSHA intends that such an employer will develop one written plan that includes different policies and procedures for vaccinated and unvaccinated employees. The requirements of paragraphs (e), (f), (h), and (j) should be addressed in the policy regardless of the vaccination requirements adopted by the employer.

As with all elements of the written plan, an effective written plan will explain the testing requirements contained in paragraph (g) for unvaccinated employees, and how the employer will implement and enforce those policies. As described in paragraph (g)(1), the testing requirements differ for employees who report at least once every 7 days to a workplace compared to those who do not. Thus, the policy may describe different testing procedures for those different groups of employees, depending on how often they physically report to a workplace where other individuals are present. As described in paragraph (g)(3), the testing requirements are temporarily suspended for 90 days following a positive COVID–19 test or diagnosis. Thus, the employer's policy and procedures to implement this temporary suspension of

testing should be included in their written workplace policy. In addition to the testing requirements in paragraph (g), an effective policy must address mandatory face covering use as described in paragraph (i), including procedures for employee compliance. Employers can get more information on the requirements for paragraphs (e) through (j), and what they must do to comply with those provisions of the standard, in the relevant *Summary and Explanation* sections (see Section VI. of this preamble).

As an employer develops their written policy, they must address how the policy will apply to new employees. Although many new hires will be fully vaccinated, there should be procedures within the plan to collect information about the new employee's vaccination status, and determine when an unvaccinated new hire must be vaccinated and, for employers using a plan under paragraph (d)(2), when COVID–19 testing and face covering use will commence if an employee remains unvaccinated. All new hires should be treated similarly to any employee who has not entered the workplace in the last seven days and will need to be fully vaccinated or provide proof of a negative COVID–19 test within the last seven days prior to entering the workplace for the first time. It is not OSHA's intention to discourage employers from hiring new employees, but rather to ensure that new employees are as well-protected from COVID–19 hazards in the workplace as current employees and are less likely to spread the virus to other employees.

An employer may have already developed and implemented a written policy on vaccination, testing, and/or face covering use to protect employees from COVID–19. It is not OSHA's intent for employers to duplicate current effective policies covering the requirements of this ETS; however, each employer with a current policy must evaluate that policy to ensure it satisfies all of the requirements of this rule. Employers with existing policies must modify and/or update their current policies to incorporate any missing required elements, and must provide information on these new updates or modifications to all employees in accordance with paragraph (j)(1). Once the employer has developed its policy pursuant to paragraph (d), the policy must be reduced to writing in order to be compliant with paragraph (d).

The note to paragraph (d) was included in recognition that, under federal law, some employees may be entitled to a reasonable accommodation from their employer, absent undue hardship. If the worker requesting a reasonable accommodation cannot be vaccinated and/or wear a face covering because of a disability, as defined by the Americans with Disabilities Act (ADA), that worker may be entitled to a reasonable accommodation. In addition, if the vaccination, and/or testing for COVID–19, and/or wearing a face covering conflicts with a sincerely held religious belief, practice or observance, a worker may be entitled to a reasonable accommodation. Such accommodations exist independently of the Occupational Safety and Health Act and, therefore, OSHA does not administer or enforce these laws. Examples of relevant federal laws under which an accommodation can be requested include the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964.

For more information, the note refers to a resource produced by the Equal Employment Opportunity Commission (EEOC), which is responsible for enforcing federal laws that prohibit employment-related discrimination based on a person's race, color, religion, sex (including pregnancy, gender identity, and sexual orientation), national origin, age (40 or older), disability, or genetic information. The EEOC resource listed in the note, What You Should Know About COVID–19 and the ADA, the Rehabilitation Act, and Other EEO Laws, available at *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws,* should be helpful to employers in navigating employees' requests for accommodations, including the process for determining a reasonable accommodation and information on undue hardship (EEOC, October 25, 2021). An additional resource that might be helpful is the CDC's informational document, *Summary Document for Interim Clinical Considerations for Use of COVID–19 Vaccines Currently Authorized in the United States* (CDC, September 29, 2021), which lists the recognized clinical contraindications to receiving a COVID–19 vaccine.

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E. Determination of Employee Vaccination Status

To comply with the requirements of the standard, it is essential that employers are aware of each employee's vaccination status. As discussed in the *Summary and Explanation* for paragraph (d) (Section VI.D. of this preamble), effective implementation and enforcement of a written vaccination policy requires the employer to know the vaccination status of all employees. Furthermore, the employer must know each employee's vaccination status in order to ensure that the vaccination, testing, and face covering requirements of the standard are met. As such, paragraph (e) includes provisions for determining each employee's vaccination status. The standard requires employers to determine the vaccination status of each employee (paragraph (e)(1)), and also to maintain records of each employee's vaccination status, preserve acceptable proof of vaccination for each employee who is fully or partially vaccinated, and maintain a roster of each employee's vaccination status (paragraph (e)(4)). As discussed more fully below, maintenance of records in accordance with this paragraph is subject to applicable legal requirements for confidentiality of medical information. Additional provisions in paragraph (e) define acceptable proof of vaccination status for vaccinated employees (paragraph (e)(2)) and provide that any employee who does not submit an acceptable form of proof of vaccination status must be treated as not fully vaccinated (paragraph (e)(3)).

Paragraph (e)(1) requires the employer to determine the vaccination status of each employee, including whether the employee is fully vaccinated. Under paragraph (e)(2), the employer must require each vaccinated employee to provide acceptable proof of vaccination status, including whether they are fully or partially vaccinated. This is an ongoing requirement for the employer (*i.e.,* the employer needs to update this information as employees proceed through the vaccination process).

Paragraph (e)(2) defines what ''acceptable proof of vaccination status'' means for purposes of the ETS, and

employers must accept any of the proofs listed in accordance with the terms of the standard and as explained more fully below. Under paragraph (e)(2), the following are acceptable for proof of vaccination: (i) The record of immunization from a health care provider or pharmacy; (ii) a copy of the U.S. CDC COVID–19 Vaccination Record Card (CDC Form MLS–319813_r, published on September 3, 2020) (CDC, October 5, 2021); (iii) a copy of medical records documenting the vaccination; (iv) a copy of immunization records from a public health, state, or tribal immunization information system; or (v) a copy of any other official documentation that contains the type of vaccine administered, date(s) of administration, and the name of the health care professional(s) or clinic site(s) administering the vaccine(s).

To be acceptable as proof of vaccination, any documentation should generally include the employee's name, type of vaccine administered, date(s) of administration, and the name of the health care professional(s) or clinic site(s) administering the vaccine(s). In some cases, state immunization records may not include one or more of these data fields, such as clinic site; in those circumstances, an employer can still rely upon the State immunization record as acceptable proof of vaccination. OSHA notes that clinic sites can include temporary vaccination facilities used during large vaccine distribution campaigns, such as schools, churches, or sports stadiums. Copies, including digital copies, of the listed forms of proof are acceptable means of documentation so long as they clearly and legibly display the necessary information. Digital copies can include, for example, a digital photograph, scanned image, or PDF of an acceptable form of proof. Some state governments are utilizing digital COVID–19 vaccine records showing the same information as the U.S. CDC COVID–19 Vaccination Record Card (CDC Form MLS–319813_r, published on September 3, 2020) and providing quick response (QR) codes that when scanned will provide the same information (see, *e.g.,* New York State Government, n.d., Retrieved October 4, 2021). In certain states, the QR code confirms the vaccine record as an official record of the state (see, *e.g.,* State of California, n.d., Retrieved October 7, 2021) and therefore would provide acceptable proof of vaccination under the ETS (see paragraph (e)(2)(iv)). However, as discussed later, the employer must retain a copy of the vaccination information retrieved when the QR code is scanned, not just the QR code itself, to comply with paragraph (e)(4). In requesting proof of vaccination, the employer must take care to comply with any applicable Federal laws, including requirements under the Privacy Act, 5 U.S.C. 552a, and the Americans with Disabilities Act (ADA), 42 U.S.C. 12101 et seq.

Each employee who has been partially or fully vaccinated should be able to provide one of the forms of acceptable proof listed above (paragraphs (e)(2)(i)–(e)(2)(v)). An employee who does not possess their COVID–19 vaccination record (*e.g.,* because it was lost or stolen) should contact their vaccination provider (*e.g.,* local pharmacy, physician's office) to obtain a new copy or utilize their state health department's immunization information system. In instances where an employee is unable to produce acceptable proof of vaccination under paragraphs (e)(2)(i)–(e)(2)(v), paragraph (e)(2)(vi) provides that a signed and dated statement by the employee will be acceptable. The employee's statement must: (A) Attest to their vaccination status (fully vaccinated or partially vaccinated); (B) attest that they have lost or are otherwise unable to produce proof required by the standard; and (C) include the following language: ''*I declare (or certify, verify, or state) that this statement about my vaccination status is true and accurate. I understand that knowingly providing false information regarding my vaccination status on this form may subject me to criminal penalties.*'' The note to paragraph (e)(2)(vi) explains that an employee who attests to their vaccination status should, to the best of their recollection, include the following information in their attestation: The type of vaccine administered; date(s) of administration; and the name of the health care professional(s) or clinic site(s) administering the vaccine(s). For example, some of the information may be easier to recall, such as receiving a vaccine at a mass vaccination site or local pharmacy, while the dates of administration might only be remembered as falling within a particular month or months. OSHA understands that employees may not be able to recall certain information, such as the type of vaccine received. Employees providing attestations should include as much of this information as they can remember to the best of their ability.

Any statement provided under paragraph (e)(2)(vi) must include an attestation that the employee is unable to produce another type of proof of vaccination (paragraph (e)(2)(vi)(B)). Thus, before an employee statement will be acceptable for proof of vaccination under paragraph (e)(2)(vi), the employee must have attempted to secure alternate forms of documentation via other means (*e.g.,* from the vaccine administrator or their state health department) and been unsuccessful in doing so. The agency recognizes that securing vaccination documentation may be challenging for some members of the workforce, such as migrant workers, employees who do not have access to a computer, or employees who may not recall who administered their vaccines (*e.g.,* if the vaccination was provided at a temporary location, such as a church, or during a state or local mass vaccination campaign). Thus, for employees who have no other means of obtaining proof of vaccination, the standard permits employers to accept attestations meeting the requirements in paragraph (e)(2)(vi) as proof of vaccination. However, employers should explain to their employees that they need to produce vaccination proof through the other means listed in paragraph (e)(2), such as by contacting the vaccination administrator, if they are able to do so. Once the employee has provided a signed and dated attestation that meets the requirements of paragraph (e)(2)(vi), the employer no longer needs to seek out one of the other forms of vaccination proof for that employee and, depending on the content of the attestation, the employer may consider that employee either fully or partially vaccinated for purposes of the ETS.

Recently, there has been evidence of fraud associated with people attesting to their vaccination status (Bergal, September 16, 2021). While employers may not invite or facilitate fraud, the ETS does not require employers to monitor for or detect fraud. By defining what constitutes acceptable proof of vaccination under the ETS, OSHA is ensuring that employers can accept proof meeting the requirements of paragraph (e) for purposes of compliance with the standard. However, the standard's requirements for proof of vaccination are integral to ensuring that employees are protected appropriately, either through vaccination (the preferred and most effective workplace control in this ETS), or through regular testing and use of face coverings. Thus, it is paramount that employees provide truthful information regarding their vaccination status.

As discussed in more detail in the *Summary and Explanation* for paragraph (j) (Section VI.J. of this section), 18 U.S.C. 1001(a), which provides for fines or imprisonment of generally up to 5 years for any person who ''in any matter within the

jurisdiction'' of the executive branch U.S. Government ''knowingly and willfully'' engages in any of the following:

(1) Falsifies, conceals, or covers up by any trick, scheme, or device a material fact;

(2) makes any materially false, fictitious, or fraudulent statement or representation; or

(3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry.

Similarly, the OSH Act recognizes that OSHA's ability to protect workers' safety and health hinges on truthful reporting. For that reason section 17(g) of the OSH Act subjects anyone who ''knowingly makes any false statement, representation, or certification in any application, record, report, plan, or other document filed or required to be maintained pursuant to this chapter'' to criminal penalties. 29 U.S.C. 666(g). False statements made in any proof submitted under paragraph (e)(2) of the standard could fall under either or both of 18 U.S.C. 1001 or section 17(g) of the OSH Act. And by requiring a specific declaration about the truth and accuracy of employee statements provided under paragraph (e)(2)(vi), employees who are unable to provide any means of proof other than their own attestation are being made aware that their words are being held to the same standard of truthfulness as any other record presented for proof of vaccination.

OSHA notes that these same prohibitions on false statements and documentation can apply to employers. If an employer knows that proof submitted by an employee is fraudulent, and even with this knowledge, accepts and maintains the fraudulent proof as a record of compliance with this ETS, it may be subject to the penalties in 18 U.S.C. 1001 and 17(g) of the OSH Act.

Paragraph (e)(3) provides the mechanism for employers to determine vaccination status for employees who do not submit any of the acceptable forms of proof of vaccination status. Under paragraph (e)(3), any employee who does not provide their employer with one of the acceptable forms of proof of vaccination status in paragraph (e)(2) must be treated as not fully vaccinated for the purpose of the standard. An unvaccinated employee does not need to provide any documentation regarding vaccination status under this ETS; however, failing to provide acceptable proof of vaccination status will signal the employer to consider the employee as not fully vaccinated and to note that as their status in the roster. For employers that include COVID–19 testing in their written policies under paragraph (d), employees without acceptable proof of vaccination status must submit to weekly tests (as required by paragraph (g)) and wear a face covering (as required by paragraph (i)).

Paragraph (e)(4) requires the employer to maintain a record of each employee's vaccination status and preserve acceptable proof of vaccination for each employee who is fully or partially vaccinated. As discussed previously, the employer has various options for acquiring proof of vaccination from each employee. An employer may allow employees to provide a digital copy of acceptable records, including, for example, a digital photograph, scanned image, or PDF of such a record that clearly and legibly displays the necessary vaccination information. However, to be in compliance with paragraph (e)(4), the employer must ensure they are able to maintain a record of each employee's vaccination status. Therefore, obtaining an employee's vaccination information verbally would not comply with paragraph (e)(2) or satisfy the record maintenance requirements of the standard. Similarly, the record maintenance requirements of paragraph (e)(4) cannot be fulfilled by an employee merely showing the employer their vaccination status (*e.g.,* by bringing the CDC COVID–19 vaccination card to the workplace and showing it to an employer representative or showing an employer representative a picture of the immunization records on a personal cellphone). To satisfy paragraph (e)(4), the employer must retain a copy of the documentation. As mentioned above, some states and local governments utilize QR codes to facilitate proof of vaccination. This can be an acceptable form of proof for compliance with the standard so long as the employer retains a copy of the information retrieved by scanning the QR code and maintains that record. Required records of vaccination status can be maintained physically or electronically, but the employer must ensure they have access to the records at all times.

In addition to obtaining and maintaining individual records of each employee's vaccination status and preserving acceptable proof of vaccination for each employee who is partially or fully vaccinated, under paragraph (e)(4) the employer must maintain a roster of each employee's vaccination status, subject to applicable confidentiality requirements. The roster must list all employees and clearly indicate for each one whether they are fully vaccinated, partially (not fully) vaccinated, not fully vaccinated because of a medical or religious accommodation (see Note to paragraph (d)), or not fully vaccinated because they have not provided acceptable proof of their vaccination status. As noted previously, any employee that has not provided acceptable proof of their vaccination status must be treated as not fully vaccinated. Although unvaccinated employees will not have proof of vaccination status, the standard requires the employer to include all employees, regardless of vaccination status, on the roster.

The roster allows the employer to easily access the vaccination status for any employee quickly and easily. This will be useful should the employer need to respond to a request from an employee or employee representative for the aggregate number of fully vaccinated employees at a workplace (along with the total number of employees at that workplace), as required under paragraph (l)(2). Additionally, the roster will help the employer implement the written policy developed in accordance with paragraph (d) and comply with other requirements of the ETS. And finally, the roster, which must be provided to OSHA on request (paragraph (l)(3)), will aid OSHA's ability to effectively and efficiently enforce this ETS.

The records and roster required by paragraph (e)(4) are considered to be employee medical records and must be maintained as such records in accordance with 29 CFR 1910.1020 and must not be disclosed except as required or authorized by this ETS or other federal law, including the Americans with Disabilities Act (ADA), 42 U.S.C. 12101 et seq. These records and roster are not subject to the retention requirements of 29 CFR 1910.1020(d)(1)(i) but must be maintained and preserved while this ETS remains in effect. OSHA considers vaccination records required by paragraphs (e)(2) and (e)(4) of the ETS to be employee medical records concerning the health status of an employee and is requiring this personally identifiable medical information to be maintained in a confidential manner. OSHA notes that under paragraph (e)(4), vaccination records and rosters are employee medical records, and must be treated as employee medical records under 29 CFR 1910.1020, without regard to whether the records satisfy the definition of employee medical record at 29 CFR 1910.1020(c)(6)(i).

Paragraph (e) in 29 CFR 1910.1020 includes requirements for access to employee medical records by

employees, their designated representatives, and OSHA. However, as discussed in more detail below, paragraph (l) of the ETS includes specific timeframes within which employers must make vaccine records available to employees, OSHA, and other specified individuals. Accordingly, the timeframes for providing access to employee medical records in 29 CFR 1910.1020(e) do not apply, and employers must follow the specific timeframes set forth in paragraph (l) of the ETS for providing access to vaccination records.

Additionally, 29 CFR 1910.1020(d) addresses the preservation of employee exposure and medical records. Paragraph (d)(1)(i) in section 1910.1020 generally provides that unless a specific occupational safety and health standard provides a different period of time, each employer must preserve and maintain employee medical records for at least the duration of employment plus thirty (30) years. Paragraph (e)(4) of the ETS specifically provides that the vaccination records required by the ETS are not subject to the retention requirements of 29 CFR 1910.1020(d)(1)(i). Instead, paragraph (e)(4) states that vaccination records must be maintained and preserved only so long as the ETS remains in effect.

Finally, while the provisions on timeframes for access to records and the retention provisions of 29 CFR 1910.1020 do not apply to vaccine records required by the ETS, other provisions in that regulation can still apply. For example, 29 CFR 1910.1020(h) includes requirements for the transfer of employee medical records when an employer ceases to do business.

OSHA recognizes the possibility that an employer may have already collected information about the vaccination status of employees, including proof of vaccination, prior to the effective date of this ETS. Under paragraph (e)(5), when an employer has ascertained employee vaccination status prior to the effective date of the ETS through another form of attestation or proof, and retained records of that ascertainment, the employer is exempt from the requirements in paragraphs (e)(1)–(e)(3). The exemption applies only for each employee whose *fully vaccinated* status has been documented prior to the effective date of the standard. For example, an employer may have asked each employee to self-report their vaccination status without requiring the employee to provide any form of proof. If that self-reporting was through oral conversation only, and not documented in some way, the employer is not considered to have retained records of that ascertainment for the purposes of this ETS. However, if, for example, the employer had the employees provide their vaccine information on a dated form, or through individual emails retained by the employer, or on an employer portal specifically created for employees to provide documentation status, or the employer created and retained some other means of documentation, the employer is considered to have retained records of ascertainment for the purposes of this ETS. Even if the record does not have all of the elements of the acceptable forms of proof listed in paragraph (e)(2), so long as the employer has ascertained employee vaccination status prior to the effective date of the ETS through another form of attestation or proof, and retained records of that ascertainment, the employer does not need to re-determine vaccination status (paragraph (e)(1)) or obtain proof of vaccination status (paragraph (e)(2)) for fully vaccinated employees. For purposes of paragraph (e)(4), the employer's records of vaccination status for each employee whose fully vaccinated status was previously documented constitute acceptable proof of vaccination. However, the employer must still develop a roster of each employee's vaccination status and include on that roster the employees for whom it had previously determined and retained records of vaccination status. OSHA notes that if the employer has not ascertained employee vaccination status for employees prior to the effective date of the ETS, then all requirements of paragraph (e) would apply. And all requirements of paragraph (e) also apply with respect to employees for whom the employer ascertained only partial vaccination status prior to the effective date of the ETS.

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F. Employer Support for Employee Vaccination

As discussed in the Summary and Explanation for paragraph (d) (Section VI.D. of this preamble), as well as in Grave Danger and Need for the ETS (Sections III.A. and III.B. of this preamble), vaccination is the single most efficient and effective method for protecting unvaccinated workers from the grave danger posed by COVID–19. This emergency temporary standard is therefore designed to strongly encourage vaccination. As discussed in detail below, paragraph (f) requires employers to support vaccination by providing employees reasonable time, including up to four hours of paid time, to receive each primary vaccination dose, and reasonable time and paid sick leave to recover from side effects experienced following each primary vaccination dose. For purposes of the requirements to support vaccination in paragraph (f), OSHA considers a vaccination series that meets the criteria in subparagraph (ii) of the definition of ''fully-vaccinated'' (*i.e.,* a heterologous primary series of such vaccines, receiving doses of different COVID–19 vaccines as part of one primary series) to be a primary vaccination series, along with the primary vaccination described in subparagraph (i) of that definition (see the Summary and Explanation for paragraph (c), Section VI.C. of this preamble, for more information on the definition of fully vaccinated).

Removing logistical barriers to obtaining vaccination is essential to increasing workforce vaccination rates, and one such barrier for many employees is their lack of time off of work to receive the vaccine and recover from any potential side effects (SEIU Healthcare, February 8, 2021). Employees' concerns about missing work to obtain and recover from a COVID–19 vaccination dose are well documented. In a McKinsey survey, 12% of respondents stated that the time spent away from work to get vaccinated or due to vaccine side effects was a barrier to vaccination (Azimi et al., April 9, 2021). In a survey conducted of unvaccinated adults in April 2021, a fifth of respondents said they were very or somewhat concerned that they may need to take time off to go and get the vaccine, and 48% of respondents said that they were very or somewhat concerned that they might miss work if

the vaccine side effects make them feel sick (KFF, May 6, 2021). Black and Hispanic adults were particularly worried about the potential time necessary to receive the vaccine and to recover from vaccine side effects; 64% of unvaccinated Hispanic adults and 55% of unvaccinated Black adults expressed concern that they might have to miss work due to the side effects of a COVID–19 vaccine, and 30% of Hispanic adults and 23% of Black adults were concerned that they might need to take time off work to get a COVID–19 vaccine (KFF, May 6, 2021; KFF, May 17, 2021). News and journal articles further evince this concern (Roy et al., December 29, 2020; Cleveland Documenters, 2021; Rosenberg and Stein, August 18, 2021).

This concern reflects the fact that many workers do not have access to paid time off to receive vaccination or to recover from side effects. A KFF survey found that only half of all workers reported that their employer provided them with paid time off either to get a COVID–19 vaccine or to recover from any side effects (KFF, June 30, 2021). A subsequent KFF survey found that only about one-third of workers were sure that their employer offered them paid time off to get a COVID–19 vaccine and recover from side effects (KFF, September 28, 2021). Although employee access to paid sick leave is less of a concern for employers with 100 or more employees, approximately 12% of employees in these situations do not have paid sick leave (BLS, September 2021) and in some cases, employees may have already exhausted paid sick leave they have received and would need additional time from their employers to recover from vaccine side effects.

The scarcity of paid time off for vaccination and side effect recovery is particularly acute for certain demographic groups. The June 2021 KFF survey found that only 38% of Black workers reported getting either paid time off to get a COVID–19 vaccine or to recover from side effects, and that only 41% of workers with household incomes less than $40,000 annually had access to such paid time off (KFF, June 30, 2021). Similarly, the September 2021 KFF survey found that lower-wage workers were particularly unlikely to report access to paid time off for vaccination or recovery, with only 23% of workers whose household incomes was less than $40,000 reporting that they could take paid time off to get vaccinated, and only 28% of that group reporting that they could take paid time off to recover from side effects (KFF, September 28, 2021). Lower-wage workers' lack of access to paid time off for vaccination comports with a different report indicating that, before the pandemic, about 65% of the lowest-wage workers had no access to paid sick leave, meaning that any time off for vaccination or recovery would result in lost wages for those who can least afford those losses (BLS, September 2021). The need for paid time off to receive vaccination is also particularly important for workers with disabilities and workers in rural areas because travel to and from vaccination sites may take more time or be more logistically difficult for those populations (National Safety Council, 2021).

Paying workers for the time spent to receive vaccination and to recover from side effects has proven to be an effective method for increasing vaccination rates. In June 2021, KFF found that approximately 75% of employed adults surveyed who received paid time off to get the vaccine or to recover from side effects had received at least one dose of the vaccine compared to only 51% of those surveyed who did not receive paid time off from their employer (KFF, June 30, 2021). KFF also found that employees who are provided paid time off and are encouraged by their employers to get vaccinated are more likely to get vaccinated, even after controlling for demographic characteristics that may impact vaccination uptake (KFF, June 30, 2021). Another KFF survey found that 28% of unvaccinated respondents who did not want to get the vaccine as soon as possible said that they would be more likely to obtain vaccination if their employer gave them paid time off to get vaccinated and recover from any side effects (KFF, May 6, 2021). KFF has also found that increasing access to paid leave for vaccination or recovery from side effects can also help further reduce disparities in vaccination by age and income (KFF, September 28, 2021).

In a different survey, paid time off for vaccination and the recovery period post-vaccination was the single most-influential action for encouraging employee vaccination, with 75% of respondents indicating that such paid time off would significantly or moderately increase the likelihood that they would get vaccinated (Azimi et al., April 9, 2021). Another survey of nearly 9,000 service workers across large grocery, retail, food service, pharmacy, and delivery firms, found that vaccination rates were lower than other frontline workers who also regularly work in-person and indoors, and when employers supported and facilitated vaccination, such as through providing paid time off or paid sick leave for vaccination or for recovery from side effects, employee vaccination rates were higher than if no support was provided, and in May 2021, workers with paid sick leave were 15% more likely to have gotten the vaccine than workers without such leave (Bellew et al., June 2021).

To address this barrier to vaccination, paragraph (f) requires employers to support COVID–19 vaccination by providing each employee with reasonable time, including up to four hours of paid time, to receive each primary vaccination dose, and reasonable time and paid sick leave to recover from side effects experienced following any primary vaccination dose. Providing this time is essential for all unvaccinated employees who are covered by this rule to ensure that they can receive primary vaccination dose(s) and recover from side effects without sacrificing pay or their jobs. In workplaces where employers implement a mandatory vaccination policy in accordance with paragraph (d)(1) of this rule, the requirements of paragraph (f) ensure that employees are able to comply with the mandatory vaccination policy without concern about missing work to do so. In workplaces where the employer opts out of implementing a mandatory vaccination policy in accordance with paragraph (d)(2), the requirements of paragraph (f) encourage employees to choose vaccination, and ensure that employees who choose to obtain vaccination, rather than be regularly tested for COVID–19 and wear a face covering in most situations when they work near others, are not penalized for making that choice.

Paragraph (f)(1) requires employers to support COVID–19 vaccination for each employee by providing reasonable time to each employee during work hours for each of their primary vaccination dose(s), including up to four hours of paid time, at the employee's regular rate of pay, for the purposes of vaccination. Reasonable time may include, but is not limited to, time spent during work hours related to the vaccination appointment(s), such as registering, completing required paperwork, all time spent at the vaccination site (*e.g.,* receiving the vaccination dose, post-vaccination monitoring by the vaccine provider), and time spent traveling to and from the location for vaccination (including travel to an off-site location (*e.g.,* a pharmacy), or situations in which an employee working remotely (*e.g.,* telework) or in an alternate location must travel to the workplace to receive the vaccine).

Employers are not, however, obligated by this ETS to reimburse employees for transportation costs (*e.g.,* gas money,

train/bus fare, etc.) incurred to receive the vaccination. This could include the costs of travel to an off-site vaccination location (*e.g.,* a pharmacy) or travel from an alternate work location (*e.g.,* telework) to the workplace to receive a vaccination dose.

Because employers are required to provide reasonable time for vaccination during work hours, if an employee chooses to receive a primary vaccination dose outside of work hours, employers are not required to grant paid time to the employee for the time spent receiving the vaccine during non-work hours. However, even if employees receive a primary vaccination dose outside of work hours, employers must still afford them reasonable time and paid sick leave to recover from side effects that they experience during scheduled work time in accordance with paragraph (f)(2).

An employer may make other efforts to facilitate vaccination of its employees by, for example, hosting a vaccine clinic at the workplace (*e.g.,* mobile trailer) or partnering with another entity, such as a pharmacy or healthcare provider, so that employees can be vaccinated at the workplace or at an off-site location. If an employer chooses to make the vaccine available to its employees, it must support full vaccination (*i.e.,* provide all doses in a primary vaccination, as applicable), and assure the availability of reasonable time and paid time to each employee to receive the full primary vaccination, and reasonable time and paid sick leave to recover from side effects that they may experience. Any additional costs incurred by the employer to bring vaccination on-site would be covered by the employer, though such an approach would likely reduce the amount of paid time needed for vaccine administration (but not side effects) because of reduced employee travel time.

Paragraph (f)(1) specifies that the amount of paid time that an employer is required to provide each employee to receive each primary vaccination dose is capped at four hours. OSHA has determined that four hours would provide reasonable time for most employees to get each vaccination dose. Vaccines are widely available to the public at clinics, pharmacies, and other locations across the country (see CDC, October 8, 2021). Providing four hours of paid time to receive each primary vaccination dose is consistent with OSHA's presumption of the amount of time needed to receive a vaccination dose in the June 2021 Healthcare ETS (86 FR 32598), and with the U.S. Office of Personnel Management's guidance to federal government agencies on the use of the emergency paid leave created for federal employees in the American Rescue Plan Act of 2021 (Public Law 117–2), which encouraged agencies to offer up to four hours of administrative leave per dose to cover time spent getting a vaccine dose, plus additional time if reasonably necessary, instead of having employees use emergency paid leave (OPM, April 29, 2021). OSHA expects that most employees will need less than four hours to receive a vaccination dose.

The maximum of four hours of paid time that employers must provide under paragraph (f)(1)(ii) for the administration of each primary vaccination dose cannot be offset by any other leave that the employee has accrued, such as sick leave or vacation leave. OSHA is concerned that employees forced to use their sick leave or vacation leave for vaccination would have a disincentive to gaining the health protection of vaccination. Employers must pay employees for up to four hours of time at the employee's regular rate of pay. This may be achieved by paying for the time to be vaccinated as work hours for up to four hours. Requiring employers to pay for vaccine administration is consistent with OSHA's normal approach of requiring employers to bear the costs of compliance with safety and health standards.

OSHA understands that employees may need much less than four hours to receive a primary vaccination dose, for example, if vaccinations are offered on-site. However, OSHA also understands that, in some circumstances, an employee may need more than four hours to receive a primary vaccination dose, in which case the additional time, as long as it is reasonable, would be considered unpaid but protected leave. The employer cannot terminate the employee if they use a reasonable amount of time to receive their primary vaccination doses. The employee may use other leave time that they have available (*e.g.,* sick leave or vacation time) to cover the additional time needed to receive a vaccination dose that would otherwise be unpaid.

Paragraph (f)(2) also requires employers to support COVID–19 vaccination for each employee by providing reasonable time and paid sick leave to recover from side effects experienced following any primary vaccination dose to each employee for each dose. The paid sick leave can be in the form of an employee's accrued sick leave, if available. If the employee does not have available sick leave, leave must be provided for this purpose.

Although some individuals experience no side effects from COVID–19 vaccination doses, the CDC has identified a range of side effects that other individuals may experience following a vaccination dose (CDC, April 2, 2021; CDC, September 30, 2021). Side effects may affect individuals' ability to engage in daily activities, are typically mild-to-moderate in severity, and usually go away in a few days. Common side effects include pain, redness, and swelling at the site of injection, and systemic side effects throughout the body, including tiredness, headache, muscle pain, chills, fever, and nausea. Side effects may be sufficiently severe to require the employee to take sick leave from work, but will rarely extend beyond a few days. One study found that ''unanticipated paid administrative leave was only required for 4.9% and 19.79% of individuals after the first and second doses of vaccine, respectively'' (Levi et al., September 25, 2021). Employees would not typically be expected to need leave solely to address redness or swelling at the site of injection, but it is not uncommon for vaccine recipients to require some recovery time for many of the other side effects. The CDC notes, however, that cough, shortness of breath, runny nose, sore throat, or loss of taste or smell are not consistent with post-vaccination symptoms and instead may be symptoms of COVID–19 or another infection (CDC, April 2, 2021).

If an employee already has accrued paid sick leave, an employer may require the employee to use that paid sick leave when recovering from side effects experienced following a primary vaccination dose. Additionally, if an employer does not specify between different types of leave (*i.e.,* employees are granted only one type of leave), the employer may require employees to use that leave when recovering from vaccination side effects. If an employer provides employees with multiple types of leave, such as sick leave and vacation leave, the employer can only require employees to use the sick leave when recovering from vaccination side effects. Employers cannot require employees to use advanced sick leave to cover reasonable time needed to recover from vaccination side effects under paragraph (f)(2). An employer may not require an employee to accrue negative paid sick leave or borrow against future paid sick leave to recover from vaccination side effects. In other words, the employer cannot require an employee to go into the negative for paid sick leave if the employee does not have accrued paid

sick leave when they need to recover from side effects experienced following a primary vaccination dose. Neither the paid time required to receive any vaccine dose(s) nor the paid sick leave required to recover from side effects experienced following any vaccination dose are retroactive requirements for vaccine dose(s) received prior to the promulgation of this ETS.

Paragraph (f)(2) requires employers to provide reasonable time and paid sick leave to employees to recover from side effects experienced following a primary vaccination dose, but does not specify the amount of paid sick leave that the employer is required to provide for that purpose. Employers may set a cap on the amount of paid sick leave available to employees to recover from any side effects, but the cap must be reasonable. CDC notes that although some people have no side effects, side effects, if experienced, should go away in a few days (CDC, September 30, 2021). Another study found that the average unanticipated paid administrative leave required by individuals experiencing side effects was around two days (1.66 days for the first dose and 1.39 days for the second dose) (Levi et al., September 25, 2021). Generally, OSHA presumes that, if an employer makes available up to two days of paid sick leave per primary vaccination dose for side effects, the employer would be in compliance with this requirement. When setting the cap, an employer would not be expected to account for the unlikely possibility of the vaccination resulting in a prolonged illness in the vaccinated employee (*e.g.,* a severe allergic reaction).

OSHA is aware that other federal, state, or local laws, or collective bargaining agreements, may require employers to provide employees additional paid time for vaccination and/or paid sick leave to recover from vaccination side effects. Where such an overlap exists, the requirements of this standard are satisfied so long as the employer provides each employee reasonable time and four hours of paid time to receive each primary vaccination dose, and reasonable time and paid sick leave to recover from side effects experienced following a primary vaccination dose.

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G. COVID–19 Testing for Employees Who Are Not Fully Vaccinated

Paragraph (g) of this ETS addresses employers' obligations with respect to employees who are not fully vaccinated, including the requirement to ensure unvaccinated employees are tested for COVID–19. As explained in *Need for the ETS* (Section III.B. of this preamble), OSHA strongly prefers that employers implement written mandatory vaccination policies because that is the most effective and efficient workplace control available for preventing the spread of COVID–19. However, this ETS is also necessary to protect workers who remain unvaccinated through required regular testing, use of face coverings, and removal of infected employees from the workplace, and to protect other workers from the greater likelihood that unvaccinated workers may spread COVID–19 in the workplace. People who are unvaccinated are at increased risk of becoming infected with COVID–19 and are more likely to spread the disease when compared to people who

[1] Azimi T et al. (2021, April 9). Getting to work: Employers' role in COVID–19 vaccination. *https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/getting-to-work-employers-role-in-covid-19-vaccination#* (Azimi et al., April 9, 2021)

are fully vaccinated (CDC, September 15, 2021). Additionally, people who are unvaccinated are more likely to experience severe clinical outcomes if they become infected than people who are vaccinated (Lopez Bernal et al., July 21, 2021). Therefore, routine COVID–19 testing of unvaccinated employees is necessary to identify employees with COVID–19 so they can be removed from the workplace to prevent transmission to other employees and to facilitate early medical intervention for infected employees when appropriate.

Routine testing of unvaccinated employees is necessary regardless of whether the unvaccinated employees have symptoms because SARS–CoV–2 infection is often attributable to asymptomatic and/or pre-symptomatic transmission (*i.e.,* individuals who are not exhibiting symptoms) (Bender et al., February 18, 2021; Klompas, September 2021; Johansson *et al.,* January 7, 2021; Byambasuren et al., December 11, 2020). Although less effective and efficient than vaccination, the CDC has recognized regularly testing unvaccinated employees for COVID–19 as a useful tool for identifying asymptomatic and/or pre-symptomatic infected individuals so that they can be isolated (CDC, May 4, 2021; CDC, October 7, 2021). In contrast, the CDC recommends that fully vaccinated employees with no symptoms and no known exposure should be exempt from routine testing programs (CDC, May 4, 2021). Additional information about the risks of COVID–19 transmission in vaccinated and unvaccinated workers is discussed in Grave Danger (Section III.A. of this preamble).

Testing for COVID–19 can broadly be divided into two categories: diagnostic testing and screening testing. The purpose of diagnostic testing is to identify current infection when a person has signs or symptoms consistent with COVID–19, or when a person is asymptomatic but has recent known or suspected exposure to SARS–CoV–2. The information provided by diagnostic testing can be used by a healthcare provider to diagnose or treat a patient. The purpose of screening testing is to identify infected people who are asymptomatic and do not have known, suspected, or reported exposure to COVID–19. Screening testing helps to identify unknown cases both so that measures can be taken to prevent further transmission to others (*e.g.,* removal from the workplace and home isolation) and also to allow infected, but asymptomatic, people to begin medical treatment, as appropriate, so they can better avoid the most severe outcomes of COVID–19 (*e.g.,* high risk individuals seeking monoclonal antibody treatment or anti-viral medication). Although the testing required in paragraph (g)(1) of this ETS is screening testing, both screening and diagnostic testing can help prevent the spread of COVID–19. Paragraph (g) does not preclude additional diagnostic testing if an employee shows signs or symptoms consistent with COVID–19 or has recent known or suspected exposure to SARS–CoV–2.

Both screening and diagnostic testing involve the use of viral COVID–19 tests to detect current infection, as opposed to antibody COVID–19 tests, which are used to detect whether a person has antibodies for COVID–19. A positive antibody test indicates someone has antibodies to SARS–CoV–2, the virus that causes COVID–19, which could either be the result of a prior infection with the virus or vaccination against COVID–19 (FDA, May 19, 2021; CDC, September 10, 2021). Viral tests for current infection fall into two categories: Nucleic acid amplification tests (NAATs) and antigen tests. The Food and Drug Administration (FDA) (October 6, 2021) has issued a number of Emergency Use Authorizations (EUAs) for viral COVID–19 tests. It is important to note that OSHA's definition of ''COVID–19 test'' requires that COVID–19 tests be cleared, approved, or authorized by the FDA and administered in accordance with authorized instructions, with the noted exception of not allowing tests that are both self-administered and self-read by the employee unless observed by the employer or an authorized telehealth proctor. In this regard, OSHA recognizes that it is within FDA's authority and jurisdiction to help to assure the appropriate safety, efficacy, and accuracy of COVID–19 tests. The definition of ''COVID–19 test'' has previously been discussed in the Summary and Explanation for paragraph (c) (Section VI.C. of this preamble). Additional information about the type of COVID–19 tests that would satisfy the requirements of paragraph (g) are available in that section of this preamble.

As explained above, the most effective and efficient workplace control for preventing the spread of COVID–19 is vaccination and OSHA strongly prefers that employers implement written mandatory vaccination policies. However, where employers have unvaccinated employees, regular COVID–19 screening tests are necessary so infected employees can be identified and removed from the workplace to prevent workplace transmission and to facilitate early medical intervention, when appropriate. In addition to being more likely to become infected with COVID–19, people who are unvaccinated are more likely to experience severe clinical outcomes from COVID–19 than fully vaccinated people (see *Grave Danger*, Section III.A. of this preamble). In a recent CDC Morbidity and Mortality Weekly Report (MMWR) out of Los Angeles County, the SARS–CoV–2 infection rate among unvaccinated persons was 4.9 times and the hospitalization rate was 29.2 times the rates among fully vaccinated persons (Griffin et al., August 27, 2021). As explained below, regular screening testing of individuals for COVID–19 is an effective method of identifying asymptomatic and pre-symptomatic infections. Screening testing of unvaccinated employees is necessary because symptom and temperature checks will miss both asymptomatic and pre-symptomatic infections, which is a serious problem because pre-symptomatic and asymptomatic transmission are significant drivers of the continued spread of COVID–19 (Johansson et al., January 7, 2021). Once infected employees are identified, they can be removed from the workplace, thereby reducing virus transmission to other employees.

Several studies have indicated that the time from exposure to becoming contagious for COVID–19 is shorter than the time for symptoms to develop (incubation period), meaning that individuals can transmit SARS–CoV–2 before they begin to feel ill (*i.e.,* pre-symptomatic transmission) (Nishiura et al., March 4, 2020; Tindale et al., June 22, 2020). Pre-symptomatic individuals can transmit the virus to others before they know they are sick. These individuals should isolate but would not know to do so if they are unaware of their infection. It is also possible for individuals to be infected and subsequently transmit the virus without ever exhibiting symptoms. This is called asymptomatic transmission. A meta-analysis of 351 studies from January 1, 2020, to April 2, 2021, estimated that 42.8% of those infected with the SARS–CoV–2 virus exhibited no symptoms at the time of testing and so had either asymptomatic or pre-symptomatic infections (Sah et al., August 10, 2021). In another meta-analysis of studies, which included people of all ages at risk of contracting COVID–19 who were tested regardless of presence or absence of symptoms, seventeen percent of cases never developed symptoms during entire COVID–19 infection (*i.e.,* asymptomatic infection). In those studies, a diagnosis was confirmed with

a positive result on a RT–PCR and all positive cases had a follow-up period of at least seven days to distinguish asymptomatic cases from pre-symptomatic cases (Byambasuren et al., December 11, 2020). In another study, researchers used a decision analytical model to assess the proportion of SARS–CoV–2 transmission from pre-symptomatic, never symptomatic, and symptomatic individuals in the community. Based on their modeling, they predicted that 59% of transmission came from asymptomatic transmission, including 35% from pre-symptomatic individuals and 24% from individuals who never develop symptoms (Johansson et al., January 7, 2021).

The existence of pre-symptomatic and asymptomatic infections pose serious challenges to containing the spread of SARS–CoV–2. Although the risk of asymptomatic transmission is 42% lower than from symptomatic COVID–19 patients (Byambasuren et al., December 11, 2020), asymptomatic transmission may result in more transmissions than symptomatic cases because asymptomatic persons are less likely to be aware of their infection and can unknowingly continue to spread the disease to others (Sah et al., August 10, 2021). The challenge of containing pre-symptomatic and asymptomatic SARS–CoV–2 transmission is amplified among unvaccinated individuals because, as explained above, they are more likely to become infected with COVID–19 in the first place.

Because unvaccinated employees are at higher risk of COVID–19 infection and COVID–19 transmission among individuals without symptoms is a significant driver of the spread of COVID–19, OSHA has determined it is necessary to prevent the pre-symptomatic and asymptomatic transmission of COVID–19 from unvaccinated workers, through a requirement for weekly screening testing. Screening testing with antigen tests is a rapidly evolving and important tool that can be used to reduce the spread of SARS–CoV–2 in the workplace, particularly when coupled with other COVID–19 prevention and control measures (*e.g.,* workplace removal of infected persons, proper use of face coverings) (Schulte et al., May 19, 2021). The CDC recommends screening testing of unvaccinated asymptomatic workers as a useful tool to detect COVID–19 and stop transmission quickly. Screening testing is particularly useful in areas with moderate to high community transmission of COVID–19, which is currently the overwhelming majority of the United States (CDC, October 7, 2021). In a study with a well-defined population of SARS–CoV–2 infected individuals, researchers found that frequent testing (*i.e.,* at least twice per week) maximizes the likelihood of detecting infected individuals. However, even when used weekly, rapid antigen tests still had a 76% probability of detection (*i.e.,* weekly rapid antigen tests correctly identified 76% of true positive infected COVID–19 individuals) (Smith et al., September 15, 2021). By identifying pre-symptomatic and asymptomatic unvaccinated employees, employers can remove them from the workplace to prevent those employees from spreading SARS–CoV–2 to other employees. More information about the removal requirements in this ETS is available in the *Summary and Explanation* for paragraph (h) (Section VI.H. of this preamble).

Since the incubation period for COVID–19 can be up to 14 days, the CDC recommends that screening testing be conducted at least weekly in non-healthcare workplaces (CDC, October 7, 2021; CDC, May 4, 2021). Other researchers also recognize the effectiveness of weekly screening testing to control surges of COVID–19 infections (Larremore, January 1, 2021). Consequently, in workplaces with unvaccinated employees, OSHA has set the minimum frequency of testing unvaccinated workers at seven days because the agency expects that it will be effective in slowing the spread of COVID–19 in those workplaces, when used in tandem with face coverings (paragraph (i)) and removal of infected individuals (paragraph (h)). OSHA emphasizes that each of these infection controls provides some protection from COVID–19 by itself, but that they work best when used together, layering their protective impact to boost overall effectiveness. Although some studies have shown that more regular screening testing (*e.g.,* twice weekly) would identify even more cases, OSHA has decided to require testing only on a weekly basis. This is in line with the CDC recommendations, and as noted above the evidence shows that this frequency is effective in detecting asymptomatic and pre-symptomatic cases. A more frequent testing schedule would result in significant additional costs, and OSHA is hesitant to impose these costs and depart from CDC recommendations without a fuller record generated through the benefit of notice and comment rulemaking. OSHA seeks comment on this issue. Nonetheless, it should be noted that nothing in this rule prevents screening testing from being conducted more frequently based on factors such as the level of community transmission, workplace experience with outbreaks, and type of workplace (*e.g.,* specific workplace factors such as high volume retail or critical infrastructure sector).

Early detection of COVID–19-positive employees through screening testing of unvaccinated employees also facilitates early medical intervention, when appropriate, to avoid the most severe health outcomes associated with COVID–19. Early effective treatment of disease can help avert progression to more serious illness, especially for patients at high risk of disease progression and severe illness, with the additional benefit of reducing the burden on healthcare systems (CDC, December 4, 2021). For example, anti-SARS–CoV–2 monoclonal antibodies have been shown to reduce the risk of hospitalization and death in the outpatient setting in those with mild to moderate COVID–19 symptoms and certain risk factors for disease progression. Treatment should be started as soon as possible after the patient receives a positive result on a COVID–19 test and within 10 days of symptom onset (NIH, September 24, 2021). Any COVID–19 medical treatment should be used in accordance with a licensed healthcare provider. The screening tests required by this rule will facilitate such treatment.

Pursuant to paragraph (g)(1)(i), covered employers must ensure that each employee who is not fully vaccinated and reports at least once every seven days to a workplace where other individuals (*e.g.,* coworkers, customers) are present: (A) Is tested for COVID–19 at least once every seven days; and (B) provides documentation of the most recent COVID–19 test result to the employer no later than the 7th day following the date on which the employee last provided a test result. Employers must ensure these unvaccinated employees are tested at least once every seven calendar days, regardless of their work schedule. For example, an unvaccinated part-time employee who is scheduled to work only every Monday and Tuesday must still be tested at least once every seven days. Because employees must provide documentation of their most recent COVID–19 test results to their employers no later than the 7th day following the date on which they last provided a test result, employees may want to set a schedule for their testing (*e.g.,* get a COVID–19 test every Wednesday). A consistent testing day may help employees ensure their documentation is provided every seven calendar days.

Paragraph (g)(1)(ii) addresses situations where an employee does not report to a workplace where other individuals, such as coworkers or customers, are present during a period of seven or more days (*e.g.,* when an employee is teleworking for an extended period of time). In such cases, the employer must ensure the employee is tested for COVID–19 within seven days prior to returning to the workplace and provides documentation of that test result to the employer upon return to the workplace. For example, if an unvaccinated office employee has been teleworking for two weeks but must report to the office, where other employees will be present (*e.g.,* coworkers, security officers, mailroom workers), on a specific Monday to copy and fax documents, that employee must receive a COVID–19 test within the seven days prior to the Monday and provide documentation of that test result to the employer upon return to the workplace. The employee's test must occur within the seven days before the Monday the employee is scheduled to report to the office, but it also must happen early enough to allow time for the results to be received before returning to the workplace. Similarly, unvaccinated new hires would need to be tested for COVID–19 within seven days prior to reporting to a workplace where other employees will be present and provide documentation of their test results no later than arrival on their first day of work. Since point-of-care testing that uses an antigen test allows for results within minutes, OSHA does not expect that scheduling tests or providing results to employers will be an impediment.

OSHA chose the seven-day period for employees returning to work after more than a week away from the workplace based on the evidence noted above about the effectiveness of testing at seven-day intervals. While it considered using a shorter time period in this situation, OSHA concluded that it would be less confusing for employers to use a uniform time period for both situations. OSHA was concerned that requiring different time periods in the two situations would cause confusion among both employees and supervisors implementing the program that would undermine the effectiveness of the testing scheme. OSHA seeks comment on this issue.

An employer has some discretion regarding how to satisfy its obligations under paragraph (g)(1), but those policies and procedures must be detailed in the employer's written policy pursuant to paragraph (d)(2) of this ETS. For example, the employer must specify how testing will be conducted (*e.g.,* testing provided by the employer at the workplace, employees independently scheduling tests at point-of-care locations, etc.). The employer must also specify in their policy how employees should provide their COVID–19 test results to the employer (*e.g.,* an online portal, to the human resources department). The *Summary and Explanation* for paragraph (d) (Section VI.D. of this preamble) provides additional information regarding the requirements of paragraph (d)(2) of this ETS. Test results given to the employer must contain information that identifies the worker (*i.e.,* full name plus at least one other identifier, such as date of birth), the specimen collection date, the type of test, the entity issuing the result (*e.g.,* laboratory, healthcare entity), and the test result.

If an employer is notified that an employee has a positive screening test, the employer must remove that employee from the workplace pursuant to paragraph (h)(2) of this ETS. The employee should quarantine and the employer must not allow the employee to return to the workplace until they meet the requirements in paragraphs (h)(2)(i) through (iii). More discussion of employee notification to their employer of a COVID–19 positive status and removal requirements is available in the *Summary and Explanation* for paragraph (h) (Section VI.H. of this preamble).

OSHA expects that most screening testing will be antigen testing that is conducted at point-of-care locations due to the reduced cost and faster processing time when compared to NAAT testing in laboratories. Most NAATs need to be processed in a laboratory with variable time to results (approximately 1–2 days). In contrast, most antigen tests can be processed at the point of care with results available in about 15–30 minutes (CDC, October 7, 2021). Rapid point-of-care tests are administered in various settings, such as: Physician offices, urgent care facilities, pharmacies, school health clinics, workplace health clinics, long-term care facilities and nursing homes, and at temporary locations, such as drive-through sites managed by local organizations. As explained above, COVID–19 tests that are both self-administered and self-read do not meet the definition of ''COVID–19 test'' in this ETS (unless observed by the employer or an authorized telehealth proctor) and therefore do not satisfy the testing requirements of paragraph (g).

Because antigen testing in point-of-care locations will typically produce results within minutes, the use of antigen testing should not result in an inability to provide the employer with test results in a timely fashion. However, the agency recognizes that where the employee or employer uses an off-site laboratory for testing, there may be delays beyond the employee's or employer's control. In the event that there is a delay in the laboratory reporting results and the employer permits the employee to continue working, OSHA will look at the pattern and practice of the individual employee or the employer's testing verification process and consider refraining from enforcement where the facts show good faith in attempting to comply with the standard.

OSHA has determined that employers may use pooling procedures to satisfy the requirements of screening testing under paragraph (g)(1). Pooling (also referred to as pool testing or pooled testing) means combining the same type of specimen from several people and conducting one laboratory test on the combined pool of specimens to detect SARS–CoV–2 (*e.g.,* four samples may be tested together, using only the resources needed for a single test). The advantages of pooling include preserving testing resources, reducing the amount of time required to test large numbers of specimens (increasing throughput), and lowering the overall cost of testing (CDC, June 30, 2021).

If pooling procedures are used and a pooled test result comes back negative, then all the specimens can be presumed negative with the single test. In other words, all of the employees who provided specimens for that pool test can be assumed to have a negative test result for SARS–CoV–2 infection. Therefore, documentation of the negative pooled test result would satisfy the paragraph (g)(1) documentation requirement for each employee in the pool and no additional testing is necessary. However, if the pooled test result is positive, immediate additional testing would be necessary to determine which employees are positive or negative. Each of the original specimens collected in the pool must be tested individually to determine which specimen(s) is (are) positive. If original specimens from the workers in a pooled test with a positive result are insufficient to be subsequently tested individually, those workers in the positive pool would need to be immediately re-swabbed and tested. The individual employee test results would be necessary to satisfy the employee documentation requirements of paragraph (g)(1). Where pooled testing is used (in accordance with paragraph (g)(1)), CDC and FDA procedures and

recommendations for implementing screening pooled tests should be followed (CDC, June 30, 2021; FDA, August 24, 2020). OSHA notes that only some tests are authorized for pooled testing, and should be performed per the authorization.

In a note to paragraph (g)(1), OSHA explains that this section does not require the employer to pay for any costs associated with testing. As explained in *Pertinent Legal Authority,* Section II. of this preamble, the OSH Act authorizes OSHA to require employers to bear the costs of compliance with occupational safety and health standards, but OSHA has discretion to decide whether to impose certain costs—such as those related to medical examinations or other tests—on employers ''[w]here [it determines that such costs are] appropriate.'' 29 U.S.C. 655(b)(7). OSHA has commonly required employers to bear the costs of compliance with standards as a cost of doing business, including requiring employers to bear the costs of medical examinations and procedures (see, *e.g.,* 29 CFR 1910.1018(n)(1)(i) (inorganic arsenic standard requires employers to ensure that medical examinations and procedures are provided ''without cost to the employee''); see also *United Steelworkers,* 647 F.2d at 1229–31 (discussing Lead standard's medical removal provisions and OSHA's authority for imposing cost of medical removal on employers)). Requiring employers to bear the costs of compliance makes it more likely that employees will take advantage of workplace protections (see 86 FR 32605). For example, employees are more likely to use personal protective equipment (PPE) when employers provide the PPE to their employees at no cost (see 72 FR 64342, 64344).

In this ETS, OSHA has largely required employers to bear the costs of compliance, including the typical costs associated with vaccination, but has determined that it would not be appropriate to impose on employers any costs associated with COVID–19 testing for employees who choose not to be vaccinated. As explained in *Need for the ETS,* Section III.B. of this preamble, this ETS is designed to strongly encourage vaccination because vaccination is the most efficient and effective control for protecting unvaccinated workers from the grave danger posed by COVID–19. COVID–19 testing is only required under the ETS where an employee has made an individual choice to forgo vaccination and pursue a less protective option. Given the superior protectiveness of vaccination, and OSHA's intent for this ETS to strongly encourage vaccination, requiring employers to bear the costs of COVID–19 testing would be counter-productive. As mentioned above, requiring employers to pay for workplace protections makes it more likely that employees will take advantage of that protection, and in this ETS, OSHA intends to strongly encourage employees to choose vaccination, not regular COVID–19 testing. Because employees who choose to remain unvaccinated will generally be required to pay for their own COVID–19 testing, this standard creates a financial incentive for those employees to become fully vaccinated and avoid that cost.

Although this ETS does not require employers to pay for testing, employer payment for testing may be required by other laws, regulations, or collective bargaining agreements or other collectively negotiated agreements. This section also does not prohibit the employer from paying for costs associated with testing required by paragraph (g)(1) of this section. Otherwise, the agency leaves the decision regarding who pays for the testing to the employer. Because OSHA does not specify who pays for the testing, OSHA expects that some workers and/or their representatives will negotiate the terms of payment. OSHA has also considered that some employers may choose to pay for some or all of the costs of testing as an inducement to keep employees in a tight labor market. Other employers may choose to put the full cost of testing on employees in recognition of the employee's decision not to become fully vaccinated. It is also possible that some employers may be required to cover the cost of testing for employees pursuant to other laws or regulations. OSHA notes, for instance, that in certain circumstances, the employer may be required, under the Fair Labor Standards Act, to pay for the time it takes an employee to be tested (*e.g.,* if employee testing is conducted in the middle of a work shift). The subject of payment for the costs associated with testing pursuant to other laws or regulations not associated with the OSH Act is beyond OSHA's authority and jurisdiction. As explained in a note to paragraph (d) of this ETS, under various anti-discrimination laws, workers who cannot be tested because of a sincerely held religious belief may ask for a reasonable accommodation from their employer. For more information about evaluating requests for reasonable accommodation for a sincerely held religious belief, employers should consult the Equal Employment Opportunity Commission's website: *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.*

Pursuant to paragraph (g)(2), if an employee does not provide the result of a COVID–19 test as required by paragraph (g)(1), the employer must keep the employee removed from the workplace until the employee provides a test result. This provision is imperative because workers with asymptomatic or pre-symptomatic SARS–CoV–2 infection are significant contributors to COVID–19 transmission, and screening testing will help to identify and remove those individuals from the workplace. Employees providing accurate and weekly test results to their employer is of utmost importance for preventing and reducing the transmission of COVID–19 in the workplace.

Paragraph (g)(3) provides that when an employee has received a positive COVID–19 test, or has been diagnosed with COVID–19 by a licensed healthcare provider, the employer must not require that employee to undergo COVID–19 testing for 90 days following the date of their positive test or diagnosis. This provision is specifically intended to prohibit screening testing for 90 days because of the high likelihood of false positive results that do not indicate active infection but are rather a reflection of past infection. Studies of patients who were hospitalized and recovered indicate that SARS–CoV–2 RNA can be detected in upper respiratory tract specimens for up to three months (90 days) after symptom onset (CDC, August 2, 2021; CDC, September 14, 2021). If employees were to be subjected to screening tests in such a situation it would both undermine the confidence in the COVID–19 screening tests and could result in a harm to the worker of being unnecessarily removed from the workplace and subjected to the additional burden of unnecessary tests. Where employers implement a vaccination policy that allows employees to choose to provide proof of regular testing and wear a face covering rather than getting vaccinated, the employer's policy and procedures to implement this temporary suspension of testing must be included in their written workplace policy as required by paragraph (d)(2) of this ETS.

Paragraph (g)(4) provides that the employer must maintain a record of each test result required to be provided by each employee under paragraph (g)(1) of this ETS or obtained during tests conducted by the employer. These records must be maintained in

accordance with 29 CFR 1910.1020 as an employee medical record and must not be disclosed except as required by this ETS or other federal law. However, these records are not subject to the retention requirements of 29 CFR 1910.1020(d)(1)(i) (Employee medical records), but must be maintained and preserved while this ETS remains in effect.

Additionally, paragraph (l) of this ETS includes specific timeframes for providing access to records, including the COVID–19 test results required by paragraph (g)(1). As a result, the timeframes for providing access to employee medical records in 29 CFR 1910.1020(e) do not apply. Instead, when providing access to an employee, anyone with written authorized consent from that employee, and OSHA, employers must follow the access timeframes set forth in paragraph (l) of this ETS. The *Summary and Explanation* for paragraph (l) (Section VI.L. of this preamble) contains additional information about accessing records gathered pursuant to paragraph (g)(1).

Finally, while the access timeframes in 29 CFR 1910.1020(e) and retention requirements of 29 CFR 1910.1020(d)(1)(i) do not apply to test result records required by this ETS, the other provisions in 29 CFR 1910.1020 do apply. For example, 29 CFR 1910.1020(h) includes requirements for the transfer of employee medical records when an employer ceases to do business. Like the vaccine records required by paragraph (e)(4) of this ETS, and because they concern the health status of an employee, test result records required by paragraph (g)(1) are employee medical records for purposes of 29 CFR 1910.1020. These test result records contain personally identifiable medical information and must be maintained in a confidential manner. The *Summary and Explanation* for paragraph (e) (Section VI.E. of this preamble) contains additional information about the interplay between this ETS and OSHA's regulation at 29 CFR 1910.1020.

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H. Employee Notification to Employer of a Positive COVID–19 Test and Removal

Employers can substantially reduce disease transmission in the workplace by removing employees who are confirmed to have COVID–19 based on a COVID–19 test or diagnosis by a healthcare provider. It is necessary that employees who are confirmed to have COVID–19 be removed from the workplace to prevent transmission to other employees. Several studies have focused on the impact of isolating persons with COVID–19 from others during their likely known infectious period, and those studies show that isolation is a strategy that reduces the transmission of infections. For example, Kucharski et al. (2020) found that transmission of SARS–CoV–2 would decrease by 29% with self-isolation within the household, which would extend to 37% if the entire household quarantined. Similarly, Wells et al. (2021) found that isolation of individuals at symptom onset would decrease the reproductive rate (R0) of COVID–19 from 2.5 to 1.6. Lastly, Moghadas et al. (2020) reported results that highlight the role of silent transmission, from a combination of the pre-symptomatic stage and asymptomatic infections, as the primary driver of COVID–19 outbreaks and underscore the need for mitigation strategies, including those that detect and isolate infectious individuals prior to the onset of symptoms. Isolating contagious employees from their co-workers can prevent further spread at the workplace and safeguard the health of other employees.

Paragraph (h) provides that employers must require each employee to promptly notify the employer when the employee receives a positive COVID–19 test or is diagnosed with COVID–19 by a licensed healthcare provider. This notification must occur regardless of employee vaccination status. As discussed in *Grave Danger* (Section III.A. of this preamble), exposure to SARS–CoV–2 in the workplace presents a grave danger to employees; removing those who are confirmed to have COVID–19 from the workplace mitigates that grave danger. This is true even for fully vaccinated employees since they also have the potential to transmit COVID–19 to other individuals, including other employees. Because the goal of this ETS, and the notification requirements in this paragraph, is to reduce transmission of COVID–19 in the workplace, employees are required to notify the employer of any COVID–19 positive test or diagnosis that they receive, not just positive results that are received from testing required under paragraph (g) of this ETS.

Paragraph (h)(1) states that the employer must require each employee who is COVID–19 positive to notify the employer of their COVID–19 test result or diagnosis ''promptly.'' For employees who are not at the workplace when they receive a positive COVID–19 test result or diagnosis, ''promptly'' notifying the employer means notifying the employer as soon as practicable before the employee is scheduled to start their shift or return to work. In the event that the employee is in the workplace when they receive a positive COVID–19 test result or diagnosis of COVID–19, ''promptly'' notifying the employer means notifying the employer as soon as safely possible while avoiding exposing any other individuals in the workplace.

The employer should establish notification procedures and inform employees about these procedures (see paragraph (j)(1)), so that employees are aware of the appropriate method for providing this notification to their employer. These notification procedures can be based on the employer's current protocols for employees to notify the employer if they are not able to come to work or need to leave work because of illness or injury. However the employer chooses to implement its notification procedures, it must ensure that an employee notification of a positive COVID–19 test or diagnoses results in the employee's immediate removal from the workplace, as required under paragraph (h)(2). For example, the employer may require employees to report any positive COVID–19 test or diagnosis to a company supervisor with the authority to temporarily remove the employee from the workplace. If an employer takes all steps required under this paragraph but an employee fails to report required information, the ETS does not dictate that any disciplinary action be taken against the employee. If an employer is cited by OSHA under this provision under such circumstances, the employer is entitled to contest the citation if it can establish an employee misconduct defense in accordance with applicable case law.

The notification requirement in paragraph (h)(1) is an important measure to ensure employers can take adequate steps to protect their employees from the hazard of COVID–19 because it is connected to a parallel requirement in paragraph (h)(2) to remove, from the workplace, any employee who receives a positive COVID–19 test or is diagnosed with COVID–19. It is important to remove employees who test positive or are diagnosed with COVID–19 from the workplace as soon as possible to prevent the transmission of COVID–19 to other employees. Therefore, the requirement that employees promptly inform their employer of a positive COVID–19 test result or COVID–19 diagnosis is necessary because this information allows the employer to take actions to protect other employees, including most critically by removing employees whose illness poses a direct threat of infection to other employees in the workplace.

Paragraph (h)(2) requires employers to immediately remove from the workplace any employee, regardless of vaccination status, who receives a positive COVID–19 test or is diagnosed with COVID–19 by a licensed healthcare provider. OSHA determined that directing an employee who tests positive or is diagnosed with COVID–19 to stay home until return to work criteria are achieved is critical to preventing the transmission of COVID–19 in the workplace. Similar to the notification required in paragraph (h)(1), this removal must occur regardless of employee vaccination status since someone who is fully vaccinated can still transmit COVID–19 to others, including other employees (see *Grave Danger,* Section III.A. of this preamble).

OSHA notes that, in most circumstances, any positive COVID–19 test would result in removal. However, this is not necessarily the case where an employer uses pooled COVID–19 testing, a method where one laboratory test is conducted using the specimens of several people to detect the virus that causes COVID–19 (CDC, June 30, 2021). If an employer conducts pooled testing for COVID–19, a positive pooled test result would trigger a need to immediately re-test those employees in the pool using an individual COVID–19 test because the positive pooled result would not satisfy the requirements of paragraph (g). Only those employees who test positive on their individual re-test would need to be removed from the workplace.

OSHA intends ''removal'' under paragraph (h)(2) to refer only to the temporary removal from the workplace of an employee while that employee is infectious. The requirement in paragraph (h)(2) to temporarily remove a COVID–19 positive employee from the workplace does not mean permanent removal of an employee from their position. Any time an employee is

required to be removed from the workplace under paragraph (h)(2) of this section, the employer can require the employee to work remotely or in isolation if suitable work is available and if the employee is not too ill to work. In cases where working remotely or in isolation is not possible, OSHA encourages employers to consider flexible and creative solutions, such as a temporary reassignment to a different position that can be performed by telework. However, if an employee is too ill to work, remote work should not be required, and sick leave or other leave should be made available as consistent with the employer's general policies and practices, and as may be required under applicable laws.

After an employee has been removed from the workplace as required by paragraph (h)(2), the employer must ensure that they do not return to the workplace until the employee meets one of three criteria outlined in paragraphs (h)(2)(i) through (h)(2)(iii). The purpose of these provisions is to ensure that an employee who has COVID–19 does not return to work until the risk that they will transmit the disease to others in the workplace has been minimized. Each of these provisions is based on the best scientific evidence available on when a person with COVID–19 is no longer likely to transmit the virus.

Under paragraph (h)(2)(i), the employee can return to work if they receive a negative result on a COVID–19 nucleic acid amplification test (NAAT) following a positive result on a COVID–19 antigen test (the most common screening test). There is a small possibility for employees to receive false positive test results when conducting regular screening with an antigen test. Positive results are usually highly accurate at moderate-to-high peak viral load, but false positives can occur, depending on the course of infection (FDA, April 2021). OSHA recognizes that an employee might choose to seek a NAAT test for confirmatory testing. NAATs are considered the ''gold standard'' for clinical diagnosis of SARS–CoV–2 and may have a higher sensitivity (*i.e.,* ability to correctly generate a positive result) than antigen tests (CDC, September 9, 2021). If an employee tested positive for COVID–19 via an antigen test, but then received follow-up confirmatory testing via a NAAT and the NAAT was negative, the positive antigen test can be considered a false positive and the employee can return to work (CDC, September 9, 2021). For a more detailed discussion of COVID–19 tests, see the *Summary and Explanation* for paragraph (c) (Section VI.C. of this preamble).

The employee may also return to work if they meet the return to work criteria in CDC's ''Isolation Guidance'' (incorporated by reference, § 1910.509) (CDC, February 18, 2021) as described in paragraph (h)(2)(ii). CDC's guidance states that a COVID–19 positive person can stop isolating when three criteria are met: (1) At least ten days have passed since the first appearance of the person's symptoms; (2) the person has gone at least 24 hours without a fever (without the use of fever-reducing medication); and (3) the person's other symptoms of COVID–19 are improving (excluding loss of taste and smell). If a person has tested positive but never experiences symptoms, then the person can stop isolating after ten days from the date of their positive test. These recommendations are based on scientific evidence reviewed by CDC, which indicates that levels of viral RNA in upper respiratory tract samples begin decreasing after the onset of symptoms (CDC, September 14, 2021). The rationale for including CDC's ''Isolation Guidance'' in the ETS was addressed in detail in *Need for Specific Provisions* in the agency's prior rulemaking on 1910.502 (see 86 FR 32376, 32455).

Finally, the employee may return to work, per paragraph (h)(2)(iii), if the employee receives a return-to-work recommendation from a licensed healthcare provider. The appropriate duration of removal from work for any given individual may differ depending on factors such as disease severity or the health of the employee's immune system. For this reason, the ETS permits employers to make decisions about an employee's return to work in accordance with guidance from a licensed healthcare provider (who would be better acquainted with a particular employee's condition). If a licensed healthcare provider recommends a longer period of isolation for a particular employee than the CDC's ''Isolation Guidance'' would otherwise recommend, then the employer would need to abide by that longer period rather than returning the employee to work after ten days.

OSHA's removal requirements as outlined in paragraph (h)(2) are intended to set the floor for what is required; however, OSHA encourages employers who are able to do so to have a more robust program of medical removal, as indeed some employers have already done. In addition to removal from the workplace based on a positive COVID–19 test or diagnosis of COVID–19, employers may consider removal based on COVID–19 symptoms or certain exposure or close contacts employees have had outside of the workplace. Similarly, employers may consider removing employees from the workplace if the employer learns that the employee was notified by a state or local public health authority to quarantine or isolate; the employer might even be contacted by such an authority directly. Although this ETS does not require removal from the workplace in those situations, the employer might choose to remove employees from the workplace, above and beyond what is required by this ETS.

Finally, the note to paragraph (h)(2) clarifies that this ETS does not require employers to provide paid time to any employee for removal as a result of a positive COVID–19 test or diagnosis of COVID–19; however, paid time may be required by other laws, regulations, or collective bargaining agreements or other collectively negotiated agreements. On the other hand, the ETS does not preclude employers from choosing to pay employees for time required for removal under this standard. Additionally, employers should allow their employees to make use of any accrued leave in accordance with the employer's policies and practices on use of leave. This provision, while not placing the burden on the employer to provide paid time, should not be read as depriving employees of the benefits they are normally entitled to as part of their employment.

Because it does not require employers to provide paid time to employees who are removed for a positive COVID–19 test or diagnosis of COVID–19, this ETS differs from OSHA's COVID–19 Healthcare ETS, which applies to employees in the healthcare industry who are expected to be exposed to COVID–19, and requires paid medical removal protection benefits (§ 1910.502(l)(5)) for most employees. This difference reflects the structure and focus of this ETS relative to the Healthcare ETS. The Healthcare ETS requires employees to report symptoms of COVID–19 to their employers, as well as positive COVID–19 tests or diagnoses (see § 1910.502(l)(2)), but does not require employees to be regularly tested for COVID–19. A primary function of the payment for medical removal in that standard is, therefore, to remove the potential for financial disincentives that might deter employees from reporting any signs or symptoms of COVID–19 that they experience. Because this ETS already requires testing for unvaccinated workers, which should result in employers learning of cases of COVID–19 in unvaccinated workers, and does not otherwise require

employees to report signs and symptoms of COVID–19 to their employers, OSHA found that requiring employer payment for removal was not necessary in this standard.

As the note to paragraph (h) indicates, the employer may be required to follow other laws or regulations that would require paid medical removal. For example, if an employee covered by this ETS believes they were exposed to COVID–19 in the workplace and then tested positive, that employee may be entitled to workers' compensation benefits. Workers' compensation is a system already in place to provide benefits to employees who get sick or injured on the job from occupational disease or a work-related injury. Some states have expressly clarified or expanded their workers compensation rules to allow for COVID–19 claims during the pandemic (see, *e.g.,* Industrial Commission of Arizona, May 15, 2020; Connecticut Executive Order No. 7JJJ, July 24, 2020; Minn. Stat. Ann. § 176.011 Subd. (15)(f), 2020)).

Finally, the ETS does not contain specific requirements under this paragraph for the employer to establish or maintain records of employee notifications of a positive COVID–19 test or diagnosis of COVID–19 by a licensed healthcare provider. However, should an employer determine that a reported case of COVID–19 is work-related, the employer must continue to record that information on the OSHA Forms 300, 300A, and 301, or on equivalent forms, if required to do so under 29 CFR part 1904. This also includes confirmed cases of COVID–19 identified under paragraph (h) that an employer determines are work-related. Under 29 CFR part 1904, COVID–19 is a recordable illness and employers are responsible for recording cases of COVID–19 if: (1) The case is a confirmed case of COVID–19 as defined by the Centers for Disease Control and Prevention (CDC); (2) the case is work-related as defined by 29 CFR part 1904.5; and (3) the case involves one or more of the general recording criteria in set forth in 29 CFR part 1904.7 (*e.g.,* medical treatment beyond first aid, days away from work). Under 29 CFR part 1904, employers must generally provide access to the 300 log to employees, former employees, and their representatives with the names of injured or ill employees included on the form. If, however, the employee requests that their name not be entered on the 300 log, the employer must treat their illness as a privacy concern case and may not enter their name on the log (see 29 CFR 1904.29(b)(6), (b)(7)(vi)).

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I. Face Coverings

Paragraph (i) of this standard addresses the use of face coverings. As previously discussed in *Grave Danger* (Section III.A. of this preamble), COVID–19 spreads when an infected person breathes out droplets and very small particles that contain the virus. These droplets and particles can be breathed in by other people or land on their eyes, noses, or mouth. Face coverings reduce the risk of droplet transmission of COVID–19. The CDC recommends that people who are not fully vaccinated wear a face covering (*e.g.,* a mask) in indoor public places. (CDC, July 14, 2021). Additional discussion on the efficacy of face coverings is provided below.

Face coverings are simple bi-directional barriers that tend to keep droplets, and to a lesser extent airborne particulates, on the side of the filter from which they originate. An explanation of the term ''face covering'', as used in this ETS, can be found in the *Summary and Explanation* for paragraph (c) (Section VI.C. of this preamble). The CDC (August 13, 2021) recommends unvaccinated people wear face coverings when indoors to prevent getting and spreading COVID–19 mostly by blocking large respiratory droplets from either leaving the face covering of the wearer (source control) or by preventing someone else's droplets from reaching the wearer (personal protection). The need for face coverings in workplaces applies particularly to unvaccinated workers due to their increased potential for asymptomatic and pre-symptomatic transmission of COVID–19.

The CDC Healthcare Infection Control Practices Advisory Committee's (HICPAC) ''Isolation Guidance'' for healthcare settings has long recommended facemasks, among other controls, to prevent the transmission of viruses that cause respiratory illnesses (Siegel *et al.,* 2007). Face coverings play an important dual role in protecting workers from droplet transmission of COVID–19. One of their key purposes is to function as source control. In this role, the face covering helps protect people around the wearer by reducing the number of infectious droplets released into the air by the wearer and limiting the distance traveled by any particles that are released. As a result, anyone near the wearer is exposed to fewer (if any) droplets and the transmission risk is lowered (OSHA,

January 28, 2021; Siegel *et al.,* 2007). Face coverings also provide a degree of particulate filtration to reduce the amount of inhaled particulate matter, meaning face coverings can help protect the wearer themselves, by reducing their inhalation of droplets produced by an infected person nearby (CDC, May 7, 2021; Brooks *et al.,* February 10, 2021).

The efficacy of any given face covering in either functioning as source control or protecting the wearer will depend on the construction, design, and material used for the face covering. The CDC has stated that ''masks are primarily intended to reduce the emission of virus-laden droplets (''source control''), which is especially relevant for asymptomatic or presymptomatic infected wearers who feel well and may be unaware of their infectiousness to others, and who are estimated to account for more than 50% of transmissions'' (CDC, May 7, 2021). The CDC has also stated that: ''Multi-layer cloth masks block release of exhaled respiratory particles into the environment, along with the microorganisms these particles carry. Cloth masks not only effectively block most large droplets (*i.e.,* 20–30 microns and larger) but they can also block the exhalation of fine droplets and particles (also often referred to as aerosols) smaller than 10 microns; which increase in number with the volume of speech and specific types of phonation. Multi-layer cloth masks can both block up to 50–70% of these fine droplets and particles and limit the forward spread of those that are not captured. Upwards of 80% blockage has been achieved in human experiments that have measured blocking of all respiratory droplets, with cloth masks in some studies performing on par with surgical masks as barriers for source control'' (CDC, May 7, 2021). Thus, the construction of the face covering is a significant factor in determining its efficacy at reducing COVID–19 transmission.

While face coverings are generally effective as source control, because of the potential variations in protective properties, OSHA has not considered face coverings that are not certified to a consensus standard to be personal protective equipment (PPE) under OSHA's general PPE standard (29 CFR 1910.132), as there is insufficient assurance that any given face covering is of safe design and construction for the work to be performed, which is required by the PPE standard. Despite these limitations, many of the available face coverings have proven to be effective at providing source control, and where a face covering is also effective in providing personal protection, the wearer will be at reduced risk of, and could be protected from, infection. Accordingly, over the course of the pandemic, through its guidance, OSHA has strongly encouraged workers to wear face coverings when they are in close contact with others to reduce the risk of spreading COVID–19 despite the shortcomings that have prevented the agency from considering them to be PPE that complies with the requirement of the PPE standard. To enhance the effectiveness of any face covering required by this standard, this ETS imposes certain minimum design criteria, consistent with CDC recommendations. Thus, the face covering must consist of at least two layers of material that is either tightly woven or non-woven, and the face covering must not have visible holes or openings. CDC has found face coverings that are tightly woven and made with at least two layers are more effective at filtering droplets than face coverings that are loosely woven or consist of a single layer of fabric (CDC, May 7, 2021; Ueki *et al.,* June 25, 2020).

OSHA's determination on the importance of face coverings is supported by a substantial body of evidence. As described in further detail below, consistent and correct use of face coverings is widely recognized and scientifically supported as an important evidence-based strategy for COVID–19 control. Accordingly, with specific exceptions relevant to outdoor areas and vaccinated persons, the CDC recommends everyone two years of age and older wear a face covering in public settings and when around people outside of their household (CDC, August 13, 2021). And, on January 21, 2021, President Biden issued Executive Order 13998, which recognizes the use of face coverings or facemasks as a necessary, science-based public health measure to prevent the spread of COVID–19, and therefore directed regulatory action to require that they be worn in compliance with CDC guidance while traveling on public transportation (*e.g.,* buses, trains, subway) and while at airports (Executive Order 13998, 86 FR 7205, 7205 (Jan. 21, 2021); CDC, February 2, 2021). Similarly, the World Health Organization (WHO) has recognized face coverings as a key measure in suppressing COVID–19 transmission, and thus, saving lives. The WHO observes that face coverings serve two purposes, to both protect healthy people from acquiring COVID–19 and to prevent sick people from further spreading it. Since December of 2020, the WHO has recommended that the general public wear face coverings in indoor settings and in outdoor settings where physical distancing cannot be maintained (WHO, December 1, 2020).

In the United States, several states have imposed statewide face covering mandates in order to mitigate the spread of COVID–19. One study examined data on statewide face covering mandates during March 1–October 22, 2020, and found that statewide face covering mandates were associated with a decline in weekly COVID–19–associated hospitalization growth rates by up to 5.6 percentage points for adults aged 18–64 years after mandate implementation, compared with growth rates during the 4 weeks preceding implementation of the mandate (Joo *et al.,* February 12, 2021). Similarly, another study examined the association of state-issued face covering mandates with COVID–19 cases and deaths during March 1–December 31, 2020, and found mandating face coverings was associated with a decrease in daily COVID–19 case and death growth rates within 20 days of implementation (Guy *et al.,* March 12, 2021).

School face covering policies for students, staff members, faculty, and visitors are associated with a reduction in COVID–19 outbreaks. Between July 15 and August 31, 2021, schools in Arizona were analyzed for school mask policies, which provided that all persons, regardless of vaccination status, were required to wear a mask indoors. The odds of a school-associated COVID–19 outbreak in schools without a mask requirement were 3.5 times higher than those in schools with an early mask requirement (Odds Ratio = 3.5; 95% Confidence Interval = 1.8–6.9) (Jehn *et al.,* October 1, 2021).

The effectiveness of face coverings in limiting the emission and spread of droplets has also been demonstrated in numerous studies. For example, multiple studies in which droplets were visualized while individuals were talking or a manikin was used to simulate coughs and sneezes demonstrated that two-layer face coverings limited the number of droplets released into the air, and limited the forward spread of those not captured (Fischer *et al.,* September 2, 2020; Verma *et al.,* June 30, 2020; CDC, May 7, 2021).

The effectiveness of face coverings in preventing infections was also observed in a number of epidemiological studies. For example, in June of 2020 an outbreak was studied aboard the *USS Theodore Roosevelt*, an environment notable for congregate living quarters, close working environments, and a sample of mostly young, healthy adults. The investigation found that use of face

coverings on board was associated with a 70% reduced risk of transmission, which demonstrates that the use of face coverings, especially among asymptomatic cases, can help mitigate future transmission (Payne *et al.,* June 12, 2020). Another publication, released in July of 2020, included an investigation of a high-exposure event among 139 clients exposed to two symptomatic hair stylists with confirmed cases of COVID–19. Both of the stylists and all of their clients wore face coverings during their interactions. Among 67 clients subsequently tested for COVID–19, all test results were negative; no symptomatic secondary cases were reported by any clients, including those who were not tested. The study concluded that the strict use of face coverings likely mitigated the spread of COVID–19 (Hendrix *et al.,* July 17, 2020).

Several other observational epidemiological studies have reviewed data regarding the ''real-world'' effectiveness of face covering usage. First, in a study of 124 Beijing households with one or more laboratory-confirmed case of COVID–19, face covering use by both the index patient and all family contacts before the index patient developed symptoms reduced secondary transmission (*i.e.,* infections occurring within two weeks of symptom onset in the index case) within the households by 79% (Wang *et al.,* May 11, 2020). Second, a retrospective case-control study from Thailand documented that, among more than 1,000 persons interviewed as part of contact tracing investigations, those who reported having always worn a face covering during high-risk exposures experienced a greater than 70% reduced risk of infection compared with persons who did not wear face coverings under these circumstances. The risk for infection was not significantly lower in those who reported only sometimes wearing face coverings compared to those who did not wear face coverings at all. This evidence supports the conclusion that face coverings must be worn consistently and correctly to meaningfully reduce the risk of infection (Doung-ngern *et al.,* September 14, 2020).

Community-level analyses have also confirmed the benefit of universal face covering use in: A unified hospital system (Wang *et al.,* July 14, 2020); a German city (Mitze *et al.,* June 1, 2020); a U.S. state (Gallaway *et al.,* October 6, 2020); a panel of 15 U.S. states and Washington, DC (Lyu and Wehby, June 16, 2020; Hatzius *et al.,* June 29, 2020); as well as both Canada (Karaivanov *et al.,* October 1, 2020) and the U.S. (Chernozhukov *et al.,* September 15, 2020) nationally. Each community analysis demonstrated that, following universal face covering directives from both organizational and political leadership, new infections were shown to fall significantly. These analyses have also shown reductions in mortality and the need for lockdowns, with their associated monetary/gross domestic product losses (Leffler *et al.,* December 2, 2020; Hatzius *et al.,* June 29, 2020). Additionally, multiple investigations involving infected passengers aboard flights longer than ten hours strongly suggest that face covering usage prevented in-flight transmissions, as demonstrated by the absence of infection developing in other passengers and crew in the 14 days following exposure (Schwartz *et al.,* April 14, 2020; Freedman and Wilder-Smith, September 25, 2020).

Researchers from the COVID–19 Systematic Urgent Review Group Effort investigated the effects of face coverings and eye protection on virus transmission in both healthcare and non-healthcare settings. They identified 172 observational studies for their systematic review and 44 comparative studies for their meta-analysis, including data on 25,697 COVID–19, SARS, or MERS patients. They concluded for the general public, based mainly on evidence from face covering use within households and among contacts of cases, that disposable surgical masks or face coverings (reusable multi-layer cotton face coverings) are associated with protection from viral transmission. Through the meta-analysis, combining 39 of the studies' results, they found a 14.3% reduction in the difference of anticipated absolute effect (*e.g.,* the chance of viral infection or transmission) between no face covering and face covering groups (Chu *et al.,* June 27, 2020).

Ueki et al. (June 25, 2020) evaluated the effectiveness of cotton face coverings, facemasks, and N95s (a commonly used respirator) in preventing transmission of SARS–CoV–2 using a laboratory experimental setting with manikins. The researchers found that all offerings provided some measure of protection as source control, limiting droplets expelled from both infected and uninfected wearers. For instance, when spaced roughly 20 inches apart, an uninfected person can reduce inhalation of infectious virus by 37% by wearing a cotton face covering. If only the infected person wears a cotton face covering, the amount breathed in by the uninfected recipient is reduced by 57%. However, if both individuals wear a cotton face covering, the exposure is reduced 67%. If both are wearing facemasks, exposure is reduced by 76%. When an infected individual wore an N95 respirator, exposure was reduced by 96% or, when the seams were taped, 99.7%.

As demonstrated by the studies above, proper face covering usage leads to a substantial reduction in the emission of virus-containing droplets and consequent transmission of the virus. This is especially critical for asymptomatic or pre-symptomatic infected wearers who feel well and may not be taking other preventative measures—like self-isolation—because they are unaware of their infectiousness to others. Combined, these individuals are estimated to account for more than 50% of COVID–19 transmissions (Honein et al., December 11, 2020; Moghadas et al., July 6, 2020; Johansson et al., January 7, 2021). This figure could be substantially reduced if face coverings are required, even for individuals who do not feel sick. Face covering use is also especially important in indoor spaces (Honein et al., December 11, 2020). The studies reviewed above show that face coverings reduce the release of droplets but do not completely eliminate them. CDC guidance affirms that COVID–19 pandemic control requires face covering use (Honein et al., December 11, 2020; CDC, May 7, 2021). Similarly, the WHO advises face covering use as a critical measure of a comprehensive package of prevention and control measures to limit the spread of COVID–19 (WHO, December 1, 2020).

Although increasing COVID–19 vaccination coverage remains the most effective means to achieve control of the pandemic, additional layered prevention strategies will be needed in the short term to minimize preventable morbidity and mortality among unvaccinated individuals. Unvaccinated individuals remain at substantial risk for infection, severe illness, and death, especially in areas where the level of SARS–CoV–2 community transmission is high (discussed in detail in *Grave Danger* (Section III.A. of this preamble)). Among strategies to prevent COVID–19, CDC recommends all unvaccinated individuals wear face coverings in public indoor settings. A proven effective strategy against SARS–CoV–2 transmission, beyond vaccination, includes using face coverings consistently and correctly (Christie et al., July 30, 2021).

The agency is not requiring the use of face coverings by workers who are fully vaccinated because vaccination is sufficient to reduce the grave danger to

themselves or others. While vaccination is sufficient to reduce grave danger to the workers themselves, the agency recognizes that there may still be residual risk (*e.g.,* breakthrough infections); severe health outcomes among vaccinated workers, however, are unlikely. Vaccination is also sufficient to reduce the grave danger that fully vaccinated workers present to others given the reduced likelihood of transmission (see *Grave Danger* in Section III.A. of this preamble). Nonetheless, the use of face coverings by fully vaccinated workers, while not required by this ETS, is strongly encouraged in a wide range of circumstances to reduce the overall risk of transmitting COVID–19, particularly in areas of substantial or high transmission, when indoors and when in crowded outdoor areas. The use of face coverings by customers and visitors to workplaces is also beneficial in reducing the overall risk of workplace transmission of COVID–19.

OSHA has always considered recognized consensus standards, with design and construction specifications, when determining the PPE requirements of the agency's standards. The OSH Act (29 U.S.C. 655(b)(8)) requires the agency to generally give deference to consensus standards unless setting its own specifications would better effectuate the purposes of the Act. The agency's standards generally require PPE to conform to the specifications in consensus standards through incorporation by reference (*e.g.,* eye and face protection, head protection, foot protection). ASTM released a specification standard on February 15, 2021, to establish a national standard baseline for barrier face coverings (ASTM F3502–21). OSHA considered, as required, incorporation of ASTM F3502–21 in this ETS. However, the agency has determined that it is infeasible for the timeframe of this ETS to incorporate this consensus standard or to otherwise establish additional criteria for face coverings beyond that already recommended by the CDC due to the time needed to manufacture and distribute any new product. OSHA notes the CDC's guidance on types of masks, including those that meet ASTM F3502–21 requirements, and respirators as helpful to employers and workers in selecting an appropriate product (CDC, September 23, 2021).

Relatedly, OSHA has previously established that medical facemasks are essential PPE for workers in healthcare and associated industries, and are already used by workers under both the general PPE standard (29 CFR 1910.132), and more specifically, the Bloodborne Pathogens standard (29 CFR 1910.1030). Facemasks are intended for a medical purpose, such as prevention of infectious disease transmission (including uses related to COVID–19). Facemasks can function as a barrier to protect the wearer from hazards such as splashes or large droplets of blood and bodily fluids. Facemasks, such as surgical masks, must be FDA-cleared or authorized by FDA, including under an EUA and provide a similar or greater level of protection when serving the purposes of a face covering. Respirators are another type of personal protective device that OSHA has regulated under the Respiratory Protection standard (29 CFR 1910.134).

The best available experimental and epidemiological data support consistent use of face coverings by unvaccinated workers in work settings to reduce the spread of COVID–19 through droplet transmission. As discussed in *Need for the ETS* (Section III.B. of this preamble), adopting face covering policies is necessary, as part of a strategy combined with testing, to protect employees from exposure to COVID–19. Requiring unvaccinated workers to wear face coverings in the workplace will reduce the likelihood that, in conjunction with the testing (paragraph (g)) and removal, of infected workers, (paragraph (h)) requirements, they will spread the virus to others, including other unvaccinated coworkers. Based on the proven effectiveness of face covering use, OSHA's COVID–19 ETS includes necessary provisions for required use of face coverings by unvaccinated workers and provisions to allow vaccinated workers and customers and visitors to wear face coverings or respirators as a component of reducing the overall risk of COVID–19 transmission in the workplace.

The benefits that result from the use of face coverings for preventing transmission of COVID–19 are derived from the combination of source control (*i.e.,* reducing the spread of large respiratory droplets to others by covering an infected person's mouth and nose) and some personal protection for the wearer, as was discussed above in the Need for Face Coverings section. Face coverings are a vital layer of protection, and the benefit to any given individual increases with increasing community use. Paragraph (i) contains requirements for the use of face coverings by each employee who is not fully vaccinated, as well as alternatives to face coverings (*e.g.,* facemasks, respirators) that may be acceptable in some situations (described in detail below). As defined in paragraph (c), a face covering means a covering that completely covers the nose and mouth of the wearer, excluding face shields, which is made with two or more layers of a breathable fabric that is tightly woven, is secured to the wearer's head with ties, ear loops, or elastic bands that go behind the head, and is a solid piece of material without slits, exhalation valves, visible holes, or other openings in the material. This definition encompasses face coverings that otherwise meet the definition of face covering under paragraph (c), but include clear plastic windows, such as those utilized by persons communicating with those who are deaf or hard-of-hearing or when seeing a person's mouth is otherwise important. Face coverings can be manufactured or homemade, and they can incorporate a variety of designs, structures, and materials. Face coverings can be disposable or reusable. Face coverings do not have to meet a consensus standard, although they might. Apart from any applicable FDA or NIOSH regulatory requirements that might otherwise apply, such requirements are not required solely for the purposes of meeting the requirements of this standard.

As a general rule, OSHA has authority to, and does, require employers to bear the costs for protective equipment, among other worker protections, required by an OSHA standard. See, *e.g.,* 29 CFR 1910.1018(j) (requiring the employer to provide protective clothing at no cost to the employee). However, in limited circumstances, OSHA has chosen not to require employers to pay for some forms of non-specialized protective equipment, such as every-day clothing, products providing weather-related protection, and non-specialized equipment that the employee wears off the job site. See 29 CFR 1910.132(h)(2)–(5). Like the analogous situations listed above, here employees may use their personal face coverings in a variety of circumstances on and off the job site as part of their every-day protection. Because the types of face coverings permitted under this ETS are widely used and readily available, (see *Technological Feasibility* (Section IV.A. of this preamble)), employees will have no difficulty obtaining them. OSHA is requiring employers to bear the costs for employee vaccination, because it is the more protective control, (*Need for the ETS* (Section III.B. of this preamble). OSHA does not believe it appropriate to impose the costs of personal face coverings on an employer where an employee has made an individual choice to pursue a less protective option. For these reasons, OSHA has

determined not to impose the costs of face coverings on the employer as a requirement under this ETS.

Paragraph (i)(1) requires employers to ensure that each employee who is not fully vaccinated wears a face covering when indoors or when occupying a vehicle with another person for work purposes, except (i) when an employee is alone in a room with floor to ceilings windows and a closed door. However, if that employee exits the room or another individual enters the room, they are required to wear a face covering. The second exception is (ii) for a limited time while an employee is eating or drinking at the workplace or for identification purposes in compliance with safety and security requirements. Under this exception, employees are not required to wear face coverings during the limited time while eating or drinking at the workplace. Employers may also let employees eat or drink outside where there may be more space and reduced risk of transmission. Additionally, under the exception in paragraph (i)(1)(ii), employees are not required to wear a face covering for a limited time for identification purposes in compliance with safety and security requirements. This means that an unvaccinated employee can temporarily remove their face covering when at a security checkpoint within their worksite and when identification is otherwise required.

Another exception for required face coverings is under paragraph (i)(1)(iii) for when an employee is wearing a respirator or facemask in accordance with other OSHA standards (*e.g.,* 1910.134, 1910.504, 1910.1030, 1910.502). Facemask or respirator use in accordance with other OSHA standards takes precedence over face covering use in this ETS. For example, OSHA standard 1910.1030 has requirements for facemasks in healthcare settings and requires that workers should continue to use the required facemask appropriate for that setting. Another example may include a worker who is required to use a respirator under 1910.134 for workplace exposure to harmful dusts, where effective engineering controls are not feasible; that worker should continue to use the required respirator. Employees must resume wearing a face covering when not engaged in the activity where a facemask or respirator is required as an essential part of their job. The last exception, contained in paragraph (i)(1)(iv), is for a very limited set of circumstances where employers can show that the use of the face covering is infeasible or creates a greater hazard. Situations where it is important to see an employee's mouth for reasons related to their job duties, or their job requires the use of their uncovered mouth, or when the use of a face covering presents a risk of serious injury or death to the employee, would also be covered under this provision. As has been previously discussed in *Summary and Explanation* for paragraph (d) (Section VI.D. of this preamble), OSHA recognizes that there may be certain workers who may not be able to wear a face covering due to a disability or sincerely held religious belief and are entitled to an accommodation.

If employers receive accommodation requests relating to face coverings or other protective gear, for example due to disability or religious garb or grooming, they should evaluate those requests under applicable laws (EEOC, October 25, 2021).

Paragraph (i)(2) requires that employers ensure that any face covering required to be worn by this section is: (i) Worn by the employee to fully cover the employee's nose and mouth; and (ii) replaced when wet, soiled, or damaged (*e.g.,* is ripped, has holes, or has broken ear loops). To be worn properly, face coverings must completely cover the wearer's mouth and nose and must fit snugly against the sides of the face without gaps. Gaps can let air with respiratory droplets leak in and out around the edges of the mask. Face coverings with a nose wire help to avoid issues with glasses fogging and create a snug fit. Workers can also use a mask fitter or brace over a disposable mask or a cloth mask to prevent air from leaking around the edges of the mask. To ensure face coverings are worn properly, an employer might appoint a manager or senior employee to check that each unvaccinated employee is properly wearing a face covering at the start of and throughout each shift. Many aspects of proper mask use are easily observable (*e.g.,* covering the mouth and nose, as well as no observable gaps). Additionally, employers may consider utilizing workplace announcements (email messages, safety talks, etc.) or displaying signs or posters throughout the facility about proper face covering usage.

The employer must ensure that employees replace face coverings when wet, soiled, or damaged (paragraph (i)(2)(ii)). Face coverings can become soiled by splashes, sprays, or splatters, from contact with a contaminated surface, or by touching/adjusting them with contaminated hands. Damaged face coverings may not fit properly and thus will have reduced effectiveness. Employees who work where there is potential for spills, sprays, or splashes may need to change or replace their face coverings more frequently (*e.g.,* in food, meat, or poultry processing plants; water, sanitation, or wastewater treatment facilities; or restaurants). As note 1 to paragraph (i) addresses, face shields may be worn in addition to face coverings to prevent them from getting wet and soiled. For work where face coverings are expected to become dirty or soiled less frequently, employees may only need to replace their face coverings daily (*e.g.,* in retail or office buildings). Regardless of work location, reusable face coverings can become soiled after each use and may be contaminated with bacteria and viruses, including the virus that causes COVID–19. To ensure performance and minimize the risk of contaminating employees after contact with a soiled face covering, as described previously, the CDC recommends washing them whenever they get dirty, but at least once a day. The CDC also has guidance on the selection, proper wearing, cleaning, and storage of face coverings (CDC, August 13, 2021).

The employer must not prevent any employee, regardless of vaccination status, from voluntarily wearing a face covering or facemask unless the employer can demonstrate that doing so would create a hazard (paragraph (i)(3)). While vaccination greatly reduces the risk of the most severe consequences of COVID–19 (*e.g.* hospitalizations and fatalities) to workers, it does not reduce the risk to zero and thus workers must be permitted to wear face coverings or facemasks even when not required to in order to allow the workers to further address residual risk. The agency has determined this provision is necessary because employees may themselves have additional medical risk factors that employers may or may not be aware of, and which require enhanced precautions. Similarly, employees may live with or have frequent contact with family members or others who have enhanced risk if infected with COVID–19 and thus justify assuring the employees' ability to take reasonable precautions to protect their own health and safety or that of loved ones.

Paragraph (i)(4) states that the employer must permit the employee to wear a respirator instead of a face covering whether required or not (*i.e.,* without regard to vaccination status), and the employer may provide respirators to the employee, even if not required. This means that when a face covering is not required by paragraph (i)(1), the employer must permit the employee to wear a respirator or the employer may even provide a respirator; in such circumstances, the employer must also comply with 1910.504 (the mini respiratory protection program).

Respirators, as defined in paragraph (c), are a type of PPE that are certified by NIOSH or authorized under an Emergency Use Authorization (EUA) by the FDA, and protect against airborne hazards by removing specific air contaminants from the ambient (surrounding) air or by supplying breathable air from a safe source. Respirator use can provide an additional level of comfort and protection beyond that provided by face coverings for employees in circumstances that do not require a respirator to be used. As discussed previously, the agency has determined that workers need the ability to wear PPE, even when it is not required, in order to address residual risk and due to health conditions that either they or their close contacts may have that warrant enhanced precautions. For a more in-depth description of the mini respiratory protection program, see the preamble to the Healthcare ETS (86 FR 32615–32617). OSHA intends the mini respirator protection program to be preserved for the duration of this ETS, and any references relied upon by OSHA in those sections of the Healthcare ETS are also incorporated explicitly into the rulemaking docket for this ETS.

The mini respiratory protection program is designed to strengthen employee protections with a small set of provisions for the safe use of respirators designed to be easier and faster to implement than the more comprehensive respiratory protection program under 29 CFR 1910.134. This ETS is addressing an emergency health crisis, so it is critical for employers to be able to get more employee protection in place quickly. OSHA expects that this approach will facilitate additional employee choice for the additional protection provided by respirators while reducing disincentives that may have discouraged employers from allowing or voluntarily providing respirators. A mini respirator program is therefore an important control to protect employees from the hazard posed by COVID–19.

The mini respiratory protection program is primarily intended to be used for addressing circumstances where employees are not exposed to suspected or confirmed sources of COVID–19, but where respirator use could offer enhanced protection to employees. Examples include when a respirator could offer enhanced protection in circumstances where a less protective (in terms of filtering and fit) face covering is required under the ETS (See 29 CFR 1910.501(i)(1)). The decision to use a respirator in place of a face covering could be due to the higher filter efficiency and better sealing characteristics of respirators when compared to face coverings. For additional discussion, the rationale for the mini respiratory protection program was addressed in detail in *Need for Specific Provisions* in the agency's prior rulemaking on 1910.504, and the requirements of the mini respiratory protection program section are discussed in *Summary and Explanation* in the agency's prior rulemaking on 1910.504.

As required by paragraph (i)(5), the employers must not prohibit customers or visitors from wearing face coverings. Face coverings are a vital layer of protection against the risk of COVID–19. (See the discussion earlier in this section on the benefits to individuals associated with increased community use.) This provision is necessary because increased use of face coverings also reduces the overall risk of COVID–19 transmission from the customers and visitors to workers, both unvaccinated and vaccinated alike. Additionally, it allows customers and visitors to protect their own health and safety. Employers may even want to create a policy encouraging the use of face coverings by anyone who enters the business; they are encouraged to coordinate with state and local health officials to obtain and respond appropriately to timely and accurate information (*e.g.,* level of community transmission, health system capacity, vaccination coverage, capacity for early detection of increases in COVID–19 cases, and populations at risk for severe outcomes from COVID–19). Local conditions will influence the decisions that public health officials make regarding community-level strategies. Additionally, workers and their representatives may also negotiate additional face covering measures not required by the ETS through collective bargaining agreements or other collectively negotiated agreements.

Lastly, for the reasons explained above, note 2 to paragraph (i) clarifies that this section does not require the employer to pay for any costs associated with face coverings. However, the note also makes clear that this section does not prohibit the employer from paying for costs associated with face coverings required by this section. OSHA notes that employer payment for face coverings may be required by other laws, regulations, or collective bargaining agreements or other collectively negotiated agreements. Additionally, workers and their representatives may also negotiate employer payment for face coverings not required by the ETS through collective bargaining agreements or other collectively negotiated agreements.

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J. Information Provided to Employees

In order to successfully implement the provisions of the ETS, it is critical that employers provide relevant information to employees. Employers must provide employees with the information specified in paragraph (j), an essential part of this ETS, because it helps to ensure that employees understand both their rights and responsibilities under the ETS and their employer's policies and procedures. The ETS cannot be effective if employees do not have sufficient knowledge and understanding of the requirements of the ETS, their employers' policies and procedures, information about available COVID–19 vaccines, their protections against retaliation and discrimination, and the potential penalties for knowingly providing false information to their employer.

Paragraph (j) provides that employers must provide the required information to each employee in a language and at a literacy level the employee understands. This means that if an employer has employees that speak different languages or are at different literacy levels, the employer must present information in a way that ensures each employee can understand it. This may require an employer to create different materials for different groups of employees (*e.g.,* materials in different languages). When information must be translated into different languages, employers must ensure the translation is one the employees can

understand. When an employer provides employees with the required information in a manner employees understand, they help ensure that their implementation of this ETS is successful.

The manner in which employers provide the required information to employees may vary based on the size and type of workplace. Employers have flexibility to communicate this information to employees using any effective methods that are typically used in their workplaces, and may choose any method of informing employees so long as each employee receives the information specified in the standard in a language and at a literacy level they understand. For example, an employer may provide this information to employees through email communications, printed fact sheets, or during a discussion at a regularly scheduled team meeting. To ensure comprehension of the information provided, employers can identify a point-of-contact for employees who have questions about the information provided.

Paragraphs (j)(1)–(4) specify the information that employers must provide to employees. Paragraph (j)(1) requires employers to provide each employee with information regarding the requirements of § 1910.501 and any policies and procedures the employer establishes to implement this ETS. The information provided to employees must cover any employer policies under paragraph (d), including the details of the employer's vaccination policy. Employers must also inform employees about the process that will be used to determine employee vaccination status, as required under paragraph (e). In addition, employers must inform employees about the time and pay/leave they are entitled to for vaccinations and any side effects experienced following vaccinations, as required by paragraph (f). And employers must also inform employees about the procedures they need to follow to provide notice of a positive COVID–19 test or diagnosis of COVID–19 by a licensed healthcare provider, as required under paragraph (h), as well as the procedures to be used for requesting records under paragraph (l). Employers must provide additional information to unvaccinated employees, including information about the employer's policies and procedures for COVID–19 testing and face coverings, as required by paragraphs (g) and (i), respectively.

Some employers may have informed employees about their COVID-related workplace-specific policies, *e.g.,* policies on vaccination, testing, and face coverings, prior to the effective date of this ETS. Employers may rely on any such prior communications for purposes of complying with paragraph (j)(1) to the extent that the prior communications meet the relevant requirements of paragraph (j) and there have been no changes to the relevant policies. Employers must review and evaluate the information already provided to determine whether it covers all of the information necessary under paragraph (j)(1). If previous information provided to employees did not cover all of the required elements, the employer must provide employees the information on those missing elements to come into compliance with the ETS. For example, if an employer has a mandatory vaccination policy and has already provided information to the employees on the policies and procedures the employer has established to implement that policy, and provided that information in a language and at a literacy level each employee can understand, the employer would not need to expend resources to provide that information again to meet the requirements under this ETS. However, the employer would still need to provide information to its employees about other new policies and procedures established to implement the ETS.

When an employer's policies or procedures change, the employer must provide any updated or supplemental information to employees. For example, an employer may initially opt to allow only paper copies as proof of COVID–19 test results. Over time, however, the employer may decide that it wants to accept electronic proof of test results. If that employer modifies its policy to permit employees to submit electronic proof of test results, the employer must inform employees of any new or altered policies and procedures that the employer implements as a result.

Paragraph (j)(2) requires employers to provide information to each employee about COVID–19 vaccine efficacy, safety, and the benefits of being vaccinated. To meet this requirement, employers must provide the CDC's document, ''Key Things to Know About COVID–19 Vaccines,'' available at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/keythingstoknow.html* (CDC, October 7, 2021), to each employee. The employer may choose to provide this information to employees in either an electronic or print format. The CDC currently provides this document in multiple languages; however, employers may need to provide additional translations if necessary to inform each employee of the contents of the document in a language they understand. Employers do not have any further obligations to create or provide information on vaccine efficacy, safety, or the benefits of being vaccinated beyond providing the aforementioned CDC document to each employee.

Paragraph (j)(3) requires employers to inform each employee about the requirements of 29 CFR 1904.35(b)(1)(iv) and section 11(c) of the OSH Act. These two provisions work together to protect employees from retaliation for engaging in activities protected by OSHA statute or regulation. The first of these provisions, section 1904.35(b)(1)(iv), prohibits employers from discharging or in any manner discriminating against any employee for reporting a work-related injury or illness. The second provision, section 11(c) of the OSH Act, prohibits employers from discriminating against employees for exercising rights under, or as a result of actions required by, the ETS. Section 11(c) also protects employees from retaliation for filing an occupational safety or health complaint, reporting a work-related injury or illness, or otherwise exercising any rights afforded by the OSH Act.

Retaliation takes many forms; it occurs when an employer (through a manager, supervisor, or administrator) fires an employee or takes any other type of adverse employment action against an employee for engaging in a protected activity. Adverse employment actions include discipline, reducing pay or hours, reassignment to a less desirable position, denying overtime or promotion, intimidation or harassment, and any other action that would dissuade a reasonable employee from raising a concern about a possible violation or engaging in other protected activity (see *Burlington Northern & Santa Fe Railway Co.* v. *White,* 548 U.S. 53, 57 (2006) holding, in the Title VII context, that the test for determining whether a particular employment action is materially adverse is whether it ''could well dissuade'' a reasonable person from engaging in protected activity).

The ETS does not change employers' substantive obligations under either 29 CFR 1904.35(b)(1)(iv) or section 11(c) of the OSH Act. Rather, it simply requires employers to make employees aware of these provisions and their requirements. By increasing awareness, OSHA believes that paragraph (j)(3) will prevent acts of retaliation from occurring in the workplace, encourage employees to exercise their right to the protections of the ETS, and engage

employees in actions required by the ETS.

It is critically important for employees to be aware of, and to be able to exercise, their rights under the ETS. Employee participation is essential to mitigating the spread of COVID–19 in the workplace, and fear of retaliation would undermine the effectiveness of the ETS. For example, per paragraph (f) of this ETS, employers must provide employees up to 4 hours of paid time at the employee's regular rate of pay for each vaccination dose, as well as reasonable time and paid sick leave for employees to recover from side effects experienced following any vaccination dose. If an employer fails to comply with paragraph (f) and then retaliates against employees who object, employees may be deterred from being vaccinated. Similarly, if employees fear retaliation, they will be less likely to voice concerns about unvaccinated co-workers who do not wear required face coverings (see paragraph (i)(1)). A workplace free from the threat of retaliation promotes collaboration between employers and employees and allows employers to more effectively implement the various requirements of this ETS.

OSHA has received a record number of complaints of retaliation during the COVID–19 pandemic. The agency's website shows that, as of September 26, 2021, OSHA had received 5,788 complaints of retaliation related to workplace protections from COVID–19 (OSHA, September 29, 2021). These figures indicate that some employers need to be reminded that they are legally prohibited from engaging in retaliatory actions. Additionally, employees likely need reassurance of their legal right to engage in protected activity without fear of suffering from adverse employment actions. As such, it is critical for employers to inform employees of the prohibitions against retaliation in 29 CFR 1904.35(b)(1)(iv) and section 11(c) after the effective date of the ETS, without regard to any information they may have provided previously on these anti-retaliation provisions. As with the other parts of paragraph (j), employers have flexibility regarding how they will provide the required information.

Paragraph (j)(4) requires employers to provide each employee with information regarding the prohibitions of 18 U.S.C. 1001 and Section 17(g) of the OSH Act, which provide for criminal penalties associated with knowingly supplying false statements or documentation. The first of these two provisions, 18 U.S.C. 1001(a) is described earlier in this preamble and provides for fines or imprisonment for persons who ''knowingly and willfully'' (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry. And section 17(g) of the OSH Act provides for fines up to $10,000, and imprisonment for not more than six months, or both, for anyone who ''knowingly makes any false statement, representation, or certification'' in any application, record, report, plan, or other document ''filed or required to be maintained pursuant to this chapter.'' False statements or documents made or submitted for purposes of complying with policies required by this ETS could fall under either or both of these statutory provisions.

This ETS requires that each employee provide their employer either COVID–19 vaccination documentation (paragraph (e)), or, if applicable, regular COVID–19 test results (paragraph (g)). There is a significant public health interest in ensuring employees provide this information truthfully to the employer. Employers cannot effectively implement the requirements of this ETS based on false information. By increasing awareness of the possible penalties an employee may face for misrepresenting their vaccination status or test results, OSHA intends to discourage such behavior. Employers can satisfy the requirement of paragraph (j)(4) by providing each employee with the text of the two statutory provisions in hard copy or via electronic communication (*e.g.*, email), translated as necessary into other languages, emphasizing the importance of providing truthful information about vaccine status and test results, and explaining that providing false information could be punishable under the two provisions. Employers are not required to provide further explanation of the statutory provisions or to provide legal advice.

Information requirements are routine components of OSHA standards. The inclusion of information requirements in this ETS reflects the agency's conviction, as noted above, that informed employees are essential to the implementation of any effective occupational safety and health policy or procedure. OSHA believes that informing employees about their rights and responsibilities under the ETS; the employer's policies and procedures; and the safety, efficacy, and benefits of vaccination will help increase the number of employees vaccinated and will facilitate effective implementation of the standard by employers.

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K. Reporting COVID–19 Fatalities and Hospitalizations to OSHA

OSHA has required employers to report work-related fatalities and certain work-related hospitalizations under its recordkeeping regulation since 1971. These requirements have been an important part of the agency's statutory mission to assure safe and healthful working conditions for all working people. All employers covered by the OSH Act, including employers who are partially exempt from maintaining injury and illness records, are required to comply with OSHA reporting requirements at 29 CFR 1904.39. Under OSHA's current reporting regulation, employers are required to report each work-related fatality to OSHA within 8 hours of the event, and each work-related in-patient hospitalization, amputation, and loss of an eye within 24 hours of the event.

The purpose of the reporting requirement in § 1904.39 is to provide OSHA with information to determine whether it is necessary for the agency to conduct an immediate investigation at a specific establishment. Employer reports of work-related COVID–19 fatalities and in-patient hospitalizations are an important element of the agency's efforts to reduce occupational exposure to the virus. After receiving an employer report, OSHA decides whether an inspection is needed to determine the cause of a work-related COVID–19 fatality or in-patient hospitalization, and whether any OSHA standards may have been violated. These reports are critical for the agency to respond quickly to COVID–19 exposure that may pose an ongoing risk to other employees at the worksite. Timely investigation also allows OSHA to view evidence at a workplace soon after a work-related COVID–19 fatality or in-patient hospitalization has occurred, and can make it easier for the agency to gather relevant information from others at the worksite that might be useful in

protecting other employees. Moreover, prompt inspection enables OSHA to gather information to evaluate whether its current standards adequately address the workplace hazard presented from COVID–19. The information gathered from employer reports is also used by the agency to form the basis of statistical data on the causes and remediation of work-related COVID–19 fatalities and in-patient hospitalizations.

In order to address the unique circumstances presented by COVID–19, and to facilitate OSHA investigation and better workplace health surveillance, paragraph (k)(1) requires covered employers to report each work-related COVID–19 fatality to OSHA within 8 hours of the employer learning about the fatality, and each work-related COVID–19 in-patient hospitalization to OSHA within 24 hours of the employer learning about the in-patient hospitalization. As described in more detail in the following discussion, OSHA is adding these additional COVID–19 reporting requirements because the delay in the manifestation and progression of symptoms of COVID–19 can lead to hospitalization or fatality outside the normal window for reporting those workplace events.

Paragraph (k)(1)(i) provides that employers must report each work-related COVID–19 fatality to OSHA within 8 hours of the employer learning about the fatality. Under this paragraph, an employer must make a report to OSHA within 8 hours of learning both (1) that an employee has died from a confirmed case of COVID–19, and (2) that the cause of death was the result of a work-related exposure to COVID–19. Employers are only required to report confirmed cases of COVID–19 as defined by the Centers for Disease Control and Prevention (CDC) (CDC, May 20, 2020). Typically, the cause of death is determined by the physician who was responsible for a patient who died in a hospital, although the cause of death can also be determined by others such as medical examiners or coroners (Pappas, May 19, 2020).

The requirement in paragraph (k)(1)(i) is similar to the fatality reporting requirement in OSHA's regulation at 29 CFR 1904.39(a)(1), which requires an employer to report to OSHA within 8 hours after the death of any employee as the result of a work-related incident. However, 29 CFR 1904.39(b)(6) requires employers to report a work-related fatality to OSHA only if the fatality occurs within 30 days of ''the work-related incident.'' Prior to this ETS, for purposes of reporting events involving COVID–19, OSHA interpreted the phrase ''the work-related incident'' to mean ''exposure'' in the work environment. Therefore, in order to be reportable under 29 CFR 1904.39(a)(1), a work-related fatality due to COVID–19 needed to have occurred within 30 days of an employee's exposure in the work environment. Given the possibility of long-term illness before death, the 30-day limitation for reporting fatalities to OSHA could restrict OSHA's ability to receive information about work-related COVID–19 fatalities.

To address these issues, OSHA has chosen not to apply the 30-day limitation period from 29 CFR 1904.39(b)(6) to the reporting provision in paragraph (k) (see paragraph (k)(2)). Therefore, the requirement to report these fatalities is not limited by the length of time between workplace exposure and death. The reporting of work-related COVID–19 fatalities that occur beyond 30 days from the time of exposure will enable the agency to evaluate more work-related COVID–19 fatalities to determine whether immediate investigations are needed to prevent other employees at the same worksite from being exposed to the virus. The report of these fatalities to OSHA facilitates the agency's timely tracking of this data. Accordingly, paragraph (k)(1)(i) requires employers to report each work-related COVID–19 fatality to OSHA within 8 hours of the employer learning about the fatality regardless of when the exposure in the work environment occurred.

Paragraph (k)(1)(ii) of the standard requires an employer to report each work-related COVID–19 in-patient hospitalization to OSHA within 24 hours of the employer learning about the in-patient hospitalization. Under this paragraph, and similar to OSHA's reporting regulation at 29 CFR 1904.39, an employer must make a report to OSHA within 24 hours of learning that (1) an employee has been in-patient hospitalized due to a confirmed case of COVID–19, and (2) the reason for the hospitalization was the result of a work-related exposure to the illness.

OSHA's current reporting regulation at 29 CFR 1904.39(a)(2) provides that, within 24 hours after the in-patient hospitalization of one or more employees, as the result of a work-related incident, an employer must report the in-patient hospitalization to OSHA. 29 CFR 1904.39(b)(6) requires employers to only report in-patient hospitalizations to OSHA if the hospitalization occurs within 24 hours of the work-related incident. For example, if an employee trips in the workplace and sustains an injury on Monday, but is not hospitalized until Thursday, the employer does not need to report the event. In this example, ''the work-related incident'' occurred on Monday when the employee tripped and was injured in the workplace. Also, under § 1904.39, employers must report in-patient hospitalizations to OSHA within 24 hours of knowing both that the employee has been in-patient hospitalized and that the reason for the hospitalization was the result of ''the work-related incident'' (see 29 CFR 1904.39(a)(2), (b)(7)–(b)(8)). In non-COVID cases, the work-relatedness of the injury is typically apparent immediately.

Since the beginning of the pandemic, the reporting of work-related COVID–19 in-patient hospitalizations under 29 CFR 1904.39 has presented unique challenges. As noted above, for purposes of reporting COVID–19 fatalities and in-patient hospitalizations, OSHA has interpreted the phrase ''the work-related incident'' in 29 CFR 1904.39(b)(6) to mean an employee's ''exposure'' to COVID–19 in the work environment. Thus, in order to be reportable, an in-patient hospitalization needed to occur within 24 hours of an employee's exposure to COVID–19 in the work environment. Given the incubation period of the virus, and the typical timeframe between exposure and the emergence of symptoms serious enough to require hospitalization, it is extremely unlikely for an in-patient hospitalization to occur within 24 hours of an employee's exposure to the virus.

To address these issues, paragraph (k)(1)(ii) does not limit the COVID–19 reporting requirement to only those hospitalizations that occur within 24 hours of exposure, as in 29 CFR 1904.39(b)(6). This change in the reporting requirement will result in OSHA making more determinations as to whether immediate investigations are needed at additional worksites. Given the severity of the disease, and how quickly it can spread, it is essential that remediation efforts at a workplace be undertaken immediately. As noted above, it is critical for OSHA to respond quickly to hazardous conditions where employees have been hospitalized. The elimination of the 24-hour limitation period will not only allow OSHA to receive more employer reports about work-related COVID–19 in-patient hospitalizations and, as a result, shed light on where severe COVID–19 events are occurring, but it will also enable the agency to respond more quickly and effectively to these situations. Accordingly, employers must report each work-related COVID–19 in-patient hospitalization to OSHA regardless of when the employee's exposure in the workplace occurred (paragraph

(k)(1)(ii)). But consistent with OSHA's normal reporting requirements, when hospitalization for a work-related case of COVID–19 does occur, the employer must report it within 24 hours of learning about the hospitalization.

Additionally, for purposes of this section, OSHA defines in-patient hospitalization as a formal admission to the in-patient services of a hospital or clinic for care or treatment (see 29 CFR 1904.39(b)(9) and (b)(10)). The determination as to whether an employee is formally admitted into the in-patient service is made by the hospital or clinic. Treatment in an Emergency Room only is not reportable.

I. Work-Relatedness Determinations

Given the nature of the disease, and the extent of community spread, in some cases, it may be difficult for an employer to determine whether an employee's COVID–19 illness is work-related, especially when an employee has experienced potential exposure both in and out of the workplace. For purposes of this ETS, when evaluating whether a fatality or in-patient hospitalization is the result of a work-related case of COVID–19, employers must follow the criteria in OSHA's recordkeeping regulation at 29 CFR 1904.5 for determining work-relatedness. Applying the criteria in 29 CFR 1904.5 under paragraph (k) of this ETS is consistent with how employers make work-relatedness determinations when reporting fatalities and other serious events under 29 CFR 1904.39.

Under § 1904.5, employers must consider an injury or illness to be work-related if an event or exposure in the work environment either caused or contributed to the resulting condition, or significantly aggravated a pre-existing injury or illness. An injury or illness is presumed work-related if it results from events or exposures occurring in the work environment, unless an exception in § 1904.5(b)(2) specifically applies. Under this language, an injury or illness is presumed work-related if an event or exposure in the work environment is a discernable cause of the injury or illness (see 66 FR 66,943 (December 27, 2001)).

According to 29 CFR 1904.5(b)(3), the ''work environment'' includes the employer's establishment and any other location where work is performed or where employees are present as a condition of their employment. Under 29 CFR 1904.5(b)(3), employers should evaluate the employee's work duties and environment and determine whether it is more likely than not that exposure at work caused or contributed to the illness (see 66 FR 5958–59 (January 19, 2001)).

Because of the typical incubation period of 3 to 14 days, an employee's exposure to COVID–19 will usually be determined after the fact. Employers must make reasonable efforts to acquire the necessary information to make good-faith work-relatedness determinations under this section. In addition, the employer should rely on information that is reasonably available at the time of the fatality or in-patient hospitalization.

A work-related exposure in the work environment would likely include close contact with a person known to be infected with COVID–19. For example, although work-relatedness must be determined on a case-by-case basis, if a number of COVID–19 illnesses develop among coworkers who work closely together without an alternative explanation, it is reasonable to conclude that an employee's fatality or in-patient hospitalization is work-related. On the other hand, if there is not a known exposure to COVID–19 that would trigger the presumption of work-relatedness, the employer must evaluate the employee's work duties and environment to determine whether it is more likely than not that the employee was exposed to COVID–19 during the course of their employment. Employers should consider factors such as:

- The type, extent, and duration of contact the employee had at the work environment with other people, particularly the general public.
- Physical distancing and other controls that impact the likelihood of work-related exposure.
- The extent and duration of time spent in a shared indoor space with limited ventilation.
- Whether the employee had work-related contact with anyone who exhibited signs and symptoms of COVID–19.

Since 1971, under OSHA's recordkeeping system, employers have been making work-relatedness determinations regarding workplace fatalities, injuries, and illnesses. In general, employers are in the best position to obtain information, both from the employee and the workplace, necessary to make a work-relatedness determination. Although employers may rely on experts and healthcare professionals for guidance, the determination of work-relatedness ultimately rests with the employer.

Finally, OSHA wishes to emphasize that, under OSHA's recordkeeping regulation at 29 CFR 1904, employers must record on the OSHA 300 log each work-related fatality, injury, and illness reported to OSHA under § 1904.39. The work-relatedness determination for fatality and in-patient hospitalization is no different than the requirement to determine work-relatedness when entering fatalities, injuries and illness on the OSH 300 log. Accordingly, the work-relatedness determination for reporting COVID–19 fatalities and in-patient hospitalizations is a determination that is already required to be made by the employer.

II. Time Periods for Reporting COVID–19 Fatalities and In-Patient Hospitalizations

As noted above, under paragraph (k), employers must report each work-related COVID–19 fatality or hospitalization to OSHA within the specified timeframes based on when any agent or employee of the employer becomes aware of the reportable event. For example, an employer ''learns'' of a COVID–19 fatality or in-patient hospitalization when a supervisor, receptionist, or other employee at the company receives information from a family member or medical professional about an employee fatality or in-patient hospitalization. It is the employer's responsibility to ensure that appropriate instructions and procedures are in place so that managers, supervisors, medical personnel, as well as other employees or agents of the company, who learn of an employee's death or in-patient hospitalization due to COVID–19 know that the company must make a report to OSHA.

Consistent with OSHA's regulation at 29 CFR 1904.39, the reporting clock begins to run with the occurrence of the reportable event. Under paragraph (k), in situations where the employer or the employer's agent does not learn about the work-related COVID–19 fatality or in-patient hospitalization right away, the employer must make the report to OSHA within 8 hours for a fatality, or 24 hours for an in-patient hospitalization, from the time the employer (or the employer's agent) learns about the reportable event. For example, if an employee dies from a work-related case of COVID–19 on Sunday at 6:00 a.m., but the employer does not learn about the death until Monday at 8:00 a.m., the employer has until 4:00 p.m. that day to make the report to OSHA. Similarly, if an employee is in-patient hospitalized for a work-related case of COVID–19 at 8:30 p.m. on Monday, but the employer or the employer's agent(s) does not learn about the hospitalization until 9:00 a.m. the next day (Tuesday), then the employer would be required to make the report to OSHA within 24 hours of learning of the in-patient hospitalization

(i.e., by 9:00 a.m. on Wednesday) (see 29 CFR 1904.39(b)(7)).

Likewise, if an employer does not learn right away that a reportable fatality or in-patient hospitalization is work-related, the employer must make the report to OSHA within 8 hours or 24 hours of learning that the death or in-patient hospitalization was the result of a work-related COVID–19 exposure. For example, if an employee is in-patient hospitalized for a case of COVID–19 at 9:00 a.m. on Monday, but the employer does not have enough information to make a work-relatedness determination until 11:00 a.m. on Monday, then the employer would be required to report the hospitalization within 24 hours of learning that the hospitalization was work-related (*i.e.,* by 11:00 a.m. on Tuesday) (see 29 CFR 1904.39(b)(8)).

Finally, if an employer makes a report to OSHA concerning a work-related COVID–19 in-patient hospitalization and that employee subsequently dies from the illness, the employer does not need to make an additional fatality report to OSHA.

III. How To Report COVID–19 Fatalities and In-Patient Hospitalizations and What Information Must Be Included in the Report

Paragraph (k)(2) of the standard provides that when reporting work-related COVID–19 fatalities and in-patient hospitalizations to OSHA in accordance with paragraph (k)(1), the employer must follow the requirements in 29 CFR 1904.39, except for 29 CFR parts 1904.39(a)(1)–(2) and (b)(6). As explained above, OSHA has included specific provisions for the reporting of work-related COVID–19 fatalities and in-patient hospitalizations that differ from 29 CFR 1904.39. However, when making COVID–19 fatality and in-patient hospitalization reports to OSHA, employers must follow the other reporting procedures set forth in § 1904.39. Specifically, under § 1904.39(a)(3), employers have three options for reporting work-related fatalities and in-patient hospitalizations to OSHA:

1. By telephone to the OSHA Area Office that is nearest to the site of the incident;

2. by telephone to the OSHA toll-free central telephone number, 1–800–321–OSHA (1–800–321–6742);

3. by electronic submission using the reporting application located on OSHA's public website at *www.osha.gov*.

Section 1904.39(a)(3) also allows employers to report work-related fatalities and in-patient hospitalizations to OSHA in person to the OSHA Area Office that is nearest to the site of the incident. However, because many OSHA Area Offices are closed to the public during the COVID–19 pandemic, employers must use one of the three options listed above. In addition, § 1904.39(b)(1) makes clear that, if the OSHA Area Office is closed, an employer may not report a work-related fatality or in-patient hospitalization by leaving a message on OSHA's answering machine, faxing the Area Office, or sending an email. Instead, the employer must make the report by using the 800 number or the reporting application located on OSHA's public website at *www.osha.gov.*

The other provisions in 29 CFR 1904.39 (except for 29 CFR 1904.39(a)(1)–(2) and (b)(6)) also apply to the reports required by paragraph (k). For example, employers should consult 29 CFR 1904.39(b)(2) to determine what information employers must give to OSHA when making COVID–19 fatality or in-patient hospitalization reports. Per that provision, employers must give OSHA the following information for each fatality or in-patient hospitalization: The establishment name, the location of the work-related incident, the time of the work-related incident, the type of reportable event (*i.e.,* fatality or in-patient hospitalization), the number of employees who suffered a fatality or in-patient hospitalization, the names of the employees who suffered a fatality or in-patient hospitalization, the employer's contact person and his or her phone number, and a brief description of the work-related incident.

References

Centers for Disease Control and Prevention. (2020, May 20). Reporting and Coding Deaths Due to COVID–19. *https://www.cdc.gov/nchs/covid19/coding-and-reporting.htm.* (CDC, May 20, 2020).

Pappas, S. (2020, May 19). How COVID–19 Deaths are Counted. Scientific American. *https://www.scientificamerican.com/article/how-covid-19-deaths-are-counted1/.* (Pappas, May 19, 2020).

L. Availability of Records

Section 8(c)(1) of the Act requires employers to ''make, keep and preserve, and make available to the Secretary [of Labor] or the Secretary of Health and Human Services, such records regarding his activities relating to this Act as the Secretary, in cooperation with the Secretary of Health and Human Services, may prescribe by regulation as necessary or appropriate for the enforcement of this Act or for developing information regarding the causes and prevention of occupational accidents and illnesses.'' Section 8(c)(2) of the Act specifically directs the Secretary of Labor to promulgate regulations requiring employers to maintain accurate records of work-related injuries and illnesses. Section 8(c)(3) of the Act requires employers to ''maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6 [of the Act.]'' In accordance with section 8(c), paragraph (l) of the ETS includes availability of records requirements for certain COVID–19-related records required to be created and maintained by the ETS. This paragraph provides a right of access to records by employees, employee representatives, and OSHA.

Paragraph (l)(1) specifies that the employer must make available, for examination and copying, the individual COVID–19 vaccine documentation and any COVID–19 test results required by the ETS for a particular employee to that employee and to anyone having written authorized consent of that employee by the end of the next business day after a request. Prompt employee access to this information ensures that employees have the information necessary to take an active role in their employers' efforts to prevent COVID–19 transmission in the workplace. In particular, in circumstances where employers or employees choose to have the employee's COVID–19 test results go directly to the employer, paragraph (l)(1) gives the employee access to their own records. Access to COVID–19 test results may be helpful for a requesting employee in evaluating information relevant to COVID–19 exposure, including if that exposure occurred at the workplace. Prompt production of these records can also assist employees in making personal medical decisions and seeking care from a licensed healthcare provider if necessary.

Employers should note that employee privacy is protected under the access to records provisions in paragraph (l)(1). Specifically, as noted above, paragraph (l)(1) requires employers to provide access to the vaccination records or COVID–19 test results for a particular employee to that employee or to anyone having that employee's written permission. However, it does not authorize employers to allow anyone other than the particular employee to access their records or results without the written consent of that employee (except as provided for under paragraph (l)(3)).

Paragraph (l)(2) requires the employer to make the following information available to an employee or an

employee representative on request: (1) The aggregate number of fully vaccinated employees at a workplace and (2) the total number of employees at that workplace. This information must be made available to these individuals by the end of the next business day after a request. Employers will be able to utilize the roster of each employee's vaccination status they are required to maintain under paragraph (e)(4) of this section to provide this information promptly to a requester.

Since the aggregate totals of fully vaccinated employees and total employees made available by request in paragraph (l)(2) do not contain any personal identifiable information or personal medical information, OSHA does not believe that access to these records raises any serious confidentiality or privacy concern if disclosed to employees or their representatives.

OSHA believes that access to this information will allow employees and employee representatives to calculate a percentage of fully vaccinated employees at a workplace, evaluate the efficacy of the employer's vaccination policy, raise any concerns identified to OSHA, and actively participate in the employer's vaccination efforts. Without the provision of this information to employees and their representatives, the only potential check on whether the employer is complying with the requirements of the ETS would be OSHA inspections. The agency believes that making this information available to employee representatives will help ensure compliance with the requirements of the ETS and thereby protect workers.

Consistent with 29 CFR 1904.35(a)(3), OSHA interprets the term ''employee'' as used in paragraph (l) to include former employees. In addition, for purposes of paragraph (l)(2), the term ''representative'' is intended to have the same meanings as in 29 CFR 1904.35(b)(2), which encompasses two types of employee representatives. The first is a personal representative of the employee, who is a person the employee designates, in writing, as his or her personal representative, or is a legal representative of a deceased or legally incapacitated employee. The second is an authorized representative, which is defined as an authorized collective bargaining agent of one or more employees working at the employer's worksite. In accordance with these interpretations, OSHA also interprets the phrase ''employee representative,'' as used in paragraph (l)(2), to include the personal and authorized representatives of former employees. These interpretations are limited to these provisions.

Under paragraphs (l)(1) and (l)(2), requesters are entitled to one free copy of each requested record, which is consistent with OSHA's recordkeeping regulation at 29 CFR 1904.35. The cost of providing one free copy to employees, former employees, and/or their representatives is minimal, and these individuals are more likely to access the records if it is without cost. Allowing the employer to charge for a copy of the record would only delay the production of the information. After receiving an initial, free copy of a requested record or document, an employee, former employee, or representative may be charged a reasonable fee for copying duplicative records. However, no fee may be charged for an update to a previously requested record. It should be noted that each COVID–19 test is a separate record, and, as such, the employee or the representative is entitled to one free copy of each COVID–19 test record.

Paragraph (l)(3) provides OSHA with a specific right of access. Under paragraph (l)(3)(i), employers must provide the written policy required by paragraph (d), and the aggregate numbers described in paragraph (l)(2) of this section (both the aggregate number of fully vaccinated employees at a workplace and the total number of employees at that workplace), to the Assistant Secretary for examination and copying within 4 business hours of a request. Consistent with the requirements in 29 CFR 1904.40(b)(2), if the records are maintained at a location in a different time zone, the employer may use the business hours of the establishment at which the records are located when calculating the deadline.

Providing OSHA with prompt access to the written policy and the aggregate numbers allows the agency to more rapidly focus inspections on employers that may not be in compliance with the requirements of this ETS. In addition, this information will help OSHA determine what to focus on in an investigation. For example, if an employer has established, implemented, and is enforcing a written mandatory vaccination policy under paragraph (d)(1) and their aggregate numbers indicate that their entire workforce is fully vaccinated against COVID–19, the agency might approach the investigation differently than in a workplace where the employer's written policy (under paragraph (d)(2)) allows employees to provide proof of regular testing for COVID–19 in accordance with paragraph (g) and wear a face covering in accordance with paragraph (i), instead of being fully vaccinated. This information also provides OSHA representatives with the ability to quickly check any vaccination claims made by an employer without undertaking an employee-by-employee assessment and assists OSHA representatives in their evaluation of the effectiveness of the employer's written policy.

Having this information within 4 business hours of the request helps the agency act more quickly to protect employees and preserves agency resources. In addition, the 4-hour response time is consistent with similar obligations under other OSHA recordkeeping requirements, such as the recordkeeping requirement in 29 CFR 1904.40(a).

Paragraph (l)(3)(ii) requires employers to provide all other records and other documents that are required to be maintained by this section to the Assistant Secretary for examination and copying by the end of the next business day after a request. This means that employers must allow OSHA representatives to examine and copy each employee's COVID–19 vaccine documentation (required to be maintained under paragraph (e)(4)), the roster of employee vaccination status (required to be maintained under paragraph (e)(4)), and each employee's COVID–19 test results (required to be maintained under paragraph (g)(4)), upon request.

As indicated in paragraph (c), the term Assistant Secretary includes the Assistant Secretary's designees. Consequently, the records and information required to be provided to the Assistant Secretary under paragraph (l)(3) must be given to the Assistant Secretary or their representatives, such as OSHA's Compliance Safety and Health Officers.

As noted above, section 8 of the OSH Act recognizes OSHA's right of access to records relating to employer compliance with occupational safety and health standards and regulations, including access to relevant employee medical records. OSHA does not believe that its inspectors need to obtain employee permission to access and review personally identifiable information. Gaining this permission would essentially make it impossible to obtain full access to the records in a timely manner, which is needed by OSHA to perform a meaningful workplace investigation. OSHA also has policies and procedures in place to ensure the privacy and confidentiality of employee records it accesses during inspections. Finally, without complete and timely access to the vaccine and testing

records, agency efforts to conduct immediate interventions to ensure employees are protected from COVID–19 at a specific workplace would be limited.

OSHA does not prescribe specific methods for requests for records in this ETS. Employees, employee representatives, and the Assistant Secretary and designees can submit requests in any manner that provides adequate notice of the request to the employer. This may include requests by in writing (*e.g.,* email, fax, letter), by phone, or in person.

M. Dates

To minimize transmission of COVID–19 in the workplace, it is essential that employers ensure that the provisions of this ETS are implemented as quickly as possible, but no later than the dates outlined in paragraph (m). This paragraph sets forth the effective date of the section and the compliance dates for specific requirements of the standard. The effective date for this ETS, as required by section 6(c)(1) of the OSH Act (29 U.S.C. 655(c)(1)), is the date of publication in the **Federal Register**. The compliance date for all provisions in the ETS is 30 days after the effective date, except for paragraph (g) (COVID–19 testing for employees who are not fully vaccinated), which requires compliance within 60 days of the effective date. Given the grave danger to employees from occupational exposure to COVID–19, as previously described, the effective date and compliance dates provided for this ETS are reasonable and appropriate.

For over a year and a half—since at least January 2020, when the Secretary of Health and Human Services declared COVID–19 to be a public health emergency for the entire United States—all employers have been made acutely aware of the importance of minimizing employees' exposure to COVID–19 and many have willingly joined the global response to stop the spread of COVID–19 and to protect their employees. Therefore, many employers have already been encouraging their employees to get vaccinated against COVID–19. Many employers have also instituted vaccination mandates (see *Technological Feasibility,* Section IV.A. of this preamble, for more information).

OSHA has published this ETS because there is great urgency in instituting the workplace protections OSHA has found to be necessary as quickly as possible. Unvaccinated workers are being hospitalized with COVID–19 every day, and many are dying, so it is particularly critical to remove obstacles as soon as possible for those who wish to be vaccinated. At the same time, OSHA has set the compliance dates to allow enough time for employers to obtain and read the standard, become knowledgeable about the standard's requirements, and undertake the necessary steps for compliance.

OSHA anticipates that employers will be able to implement measures to comply with most provisions of the ETS well within 30 days, pursuant to paragraph (m)(2)(i). Even in situations where an employer has not previously taken the required actions to address COVID–19 hazards in the workplace, steps such as developing a vaccination policy, determining employee vaccination status, providing support for employee vaccination, ensuring employees who are not fully vaccinated wear face coverings, and most other measures required under the standard can readily be completed within the 30-day time period. These measures do not require extensive lead times for large employers to implement. The scope of the standard is limited to employers with more than 100 employees largely because OSHA is especially confident that these employers will have the ability to implement the standard.

Paragraph (m)(2)(ii) of the ETS provides a longer period of time—60 days—for employers to comply with the requirements for COVID–19 testing in paragraph (g). Paragraph (g) requires employers to implement COVID–19 testing and reporting of results for employees who are not fully vaccinated. One reason for this extended period of time for testing is that employers may need additional time to develop policies and procedures regarding COVID–19 testing and associated recordkeeping.

Perhaps more critically, this ETS is intended to incentivize vaccination, so this delayed compliance date was established to allow sufficient time for employees to complete a COVID–19 primary vaccination before it is necessary to comply with the testing requirements in paragraph (g). The 60-day compliance period in paragraph (m)(2)(ii) provides employees with sufficient time to receive one dose of a single-dose primary vaccination (*e.g.,* Janssen (Johnson & Johnson)) or both doses of a two-dose primary vaccination series (*e.g.,* Pfizer-BioNTech, Moderna). For the Janssen COVID–19 vaccine, the primary vaccination takes 1 day to complete (CDC, August 10, 2021). Employees who receive the Janssen vaccine could therefore begin their primary vaccination at any time up to and including the 60th day from the date of publication in the **Federal Register** in order to be exempt from the testing requirements of paragraph (g). For the Pfizer-BioNTech COVID–19 vaccine, the primary vaccination series takes 21 days to complete (CDC, August 25, 2021). Employees receiving the Pfizer-BioNTech series could begin their primary vaccination series up to 39 days from the date of publication in the **Federal Register**. Finally, for the Moderna COVID–19 vaccine, the primary vaccination series takes 28 days to complete (CDC, August 23, 2021). Employees receiving the Moderna series could therefore begin their primary vaccination series up to 32 days from the date of publication in the **Federal Register**.

As specified in paragraph (m)(2)(ii), if an employee completes the entire primary vaccination within 60 days following publication in the **Federal Register**, that employee does not have to be tested under paragraph (g), even if they have not yet completed the two week waiting period that is required to meet the definition of fully vaccinated in paragraph (c). Employers must begin compliance with the testing requirements of paragraph (g) only for employees who have not yet completed primary vaccination (*i.e.,* employees who have not received any doses, employees who have received only one dose of a two-dose series) within 60 days from the date of publication in the **Federal Register**. And because employers must have their vaccination support processes (as required by paragraph (f)) in place before employees would need to initiate their primary vaccination in time to avoid testing under this section, employees will be able to avoid all testing costs required by this ETS.

Compliance with the requirements of the ETS within the specified dates is achievable. Many employers are likely already in compliance with at least some of the provisions of the ETS. Resources are also readily available to help employers achieve compliance. These resources include guidance issued by OSHA, the CDC, state and local governments, trade associations, and other organizations to help employers successfully implement vaccination, testing, and face covering requirements to minimize the transmission of COVID–19 in the workplace. OSHA therefore concludes that the compliance dates in this ETS strike a reasonable balance between incentivizing vaccination and allowing enough time for employers to comply.

Although employers are not required to comply with the requirements of this ETS until 30 days from the date of publication in the **Federal Register** (60 days for paragraph (g)), OSHA strongly encourages employers to implement the

required measures to support employee vaccination as soon as practicable. Providing support for employees to receive the COVID–19 vaccine and recover from side effects, as required in paragraph (f) of the ETS, prior to the compliance date may encourage employees to receive a COVID–19 vaccination at the earliest possible date. This would not only reduce the grave danger of COVID–19 in the workplace but also reduce burdens on both employers and employees when the compliance dates for the additional requirements for employees who are not fully vaccinated arrive.

References

Centers for Disease Control and Prevention (CDC). (2021, August 10). Janssen COVID–19 Vaccine (Johnson & Johnson). *https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html.* (CDC, August 10, 2021)

Centers for Disease Control and Prevention (CDC). (2021, August 23). Moderna COVID–19 Vaccine. *https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html.* (CDC, August 23, 2021)

Centers for Disease Control and Prevention (CDC). (2021, August 25). Pfizer-BioNTech COVID–19 Vaccine. *https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html.* (CDC, August 25, 2021)

N. Severability

OSHA's amendment to its COVID–19 ETS, Part 1910, Subpart U, includes a republication of § 1910.505, *Severability.* Section 1910.505 contains a severability clause, the primary purpose of which is to express OSHA's intent that if any section or provision of the COVID–19 ETS is held invalid or unenforceable or is stayed or enjoined by any court of competent jurisdiction, the remaining sections or provisions should remain effective and operative. OSHA is including 29 CFR 1910.505 as part of this ETS for the same reasons the agency included the provision in the Healthcare ETS, and OSHA intends for it to have the same purposes and effects as those expressed in the preamble to the Healthcare ETS (86 FR 32617–32618), which is hereby included in the record for this ETS.

Because subpart U is the result of two separate ETSs published at different times and subject to different time frames, but OSHA intends for both ETSs to be subject to the same principles of severability, OSHA has relied on the same centralized severability section for both for efficiency. For the benefit of the reader and for administrative convenience, this centralized severability section is located in the same subpart as the other provisions of the ETS. While either ETS remains in effect, it is OSHA's intent that 29 CFR 1910.505 remain in subpart U and operative as to either ETS still in effect. If both ETSs are not made permanent, 29 CFR 1910.505 will cease to have effect along with the rest of subpart U. If either ETS is made permanent, OSHA will provide notice at that time of the agency's intended application of 29 CFR 1910.505 to the newly permanent standard. For example, if 29 CFR 1910.502 becomes permanent because it has been finalized, but 29 CFR 1910.501 remains a temporary requirement because it is not yet finalized, 29 CFR 1910.505 would remain in subpart U and operative as to 29 CFR 1910.501 and the agency would separately provide notice of how severability is intended to apply to the newly permanent 29 CFR 1910.502.

O. Incorporation by Reference

OSHA's amendment to its COVID–19 ETS, Part 1910, Subpart U, includes the addition of § 1910.501, *Vaccination, Testing, and Face Coverings.* This section incorporates by reference CDC's ''Isolation Guidance.''

This document, listed below, will be fixed in time and made publicly available. OSHA had previously incorporated this same document into 29 CFR 1910.502 and listed it in subpart U's incorporation by reference (IBR) section, 29 CFR 1910.509. Because subpart U is the result of two separate ETSs published at different times and subject to different time frames, but both incorporate documents by reference, OSHA has relied on the same centralized IBR section for both. For the benefit of the reader and for administrative convenience, this centralized IBR section is located in the same subpart as the other provisions of the ETS.

While either ETS remains in effect, it is OSHA's intent that 29 CFR 1910.509 remain in subpart U. If both ETSs are not made permanent, 29 CFR 1910.509 will cease to have effect along with the rest of subpart U. If either ETS is made permanent, OSHA intends to recodify the relevant standards for that ETS from 29 CFR 1910.509 into 29 CFR 1910.6, the centralized IBR section for part 1910. For example, if 29 CFR 1910.502 becomes permanent because it has been finalized, but 29 CFR 1910.501 remains a temporary requirement because it is not yet finalized, OSHA would relocate all of 29 CFR 1910.502's incorporated documents into 29 CFR 1910.6, but 29 CFR 1910.509 would remain in subpart U and would list the one document incorporated by reference into 29 CFR 1910.501.

In this section, OSHA includes a list of the titles, editions/versions, and years of the incorporated documents. Stakeholders may consult 29 CFR 1910.509 both to locate all of the documents incorporated by reference in subpart U (the paragraph in which the document is incorporated is listed there) and to find more details regarding how to locate the specific consensus standard and guidelines that have been incorporated by reference in the ETS.

OSHA recognizes that the Centers for Disease Control and Prevention (CDC) may update their guidelines based on the most current available scientific evidence, but OSHA is only requiring compliance with CDC's ''Isolation Guidance'' as incorporated by reference, which is fixed in time as of February 18, 2021.

As discussed in the preamble of the Healthcare ETS at 86 FR 32619, CDC's guidance, including its ''Isolation Guidance,'' is not expressed in mandatory terms. As such, OSHA has determined it is not sufficiently protective or a meaningful alternative to a mandatory standard. OSHA has reviewed this guidance and determined that compliance with the safety measures and specific instructions in CDC's ''Isolation Guidance'' is important to protect workers who work for employees with over 100 employees. For the same reasons as described in the Healthcare ETS (86 FR 32619), OSHA is incorporating this guidance by reference, and compliance with the recommendations will be mandatory. OSHA will be able to cite employers who do not follow them. Compliance with all applicable provisions of the incorporated document is required where the provisions into which they are incorporated are mandatory, whether the incorporated document sets out its directions in mandatory language or recommendations. OSHA recognizes that this document incorporated by reference into the ETS may become outdated when newer versions are published or other entities revise those documents. In that case, OSHA will work quickly to update the ETS through a new rulemaking or issue enforcement guidance, as appropriate. But OSHA also has a longstanding de minimis enforcement policy to allow employers to rely on documents that are at least as protective.

OSHA is incorporating by reference (in 29 CFR 1910.509) the material below. A brief description of the guidance is provided in the text below. A description of its use can be found in the Regulatory Text, and *Summary and Explanation* (Section VI. of this

preamble), where the guidance is referenced.

Regulatory Text—§§ 1910.501(h); 1910.502(l)

CDC's Isolation Guidance (2021): This guidance provides steps to take when someone is experiencing COVID–19 symptoms and/or tested positive for COVID–19. This document is available at *www.osha.gov/coronavirus/ets/ibr.*

The CDC document is available at no cost through the contact information listed above. In addition, in accordance with § 1910.509(a)(1), this guidance is available for inspection at any Regional Office of the Occupational Safety and Health Administration (OSHA), or at the OSHA Docket Office, U.S. Department of Labor, 200 Constitution Avenue NW, Room N–3508, Washington, DC 20210; telephone: 202–693–2350 (TTY number: 877–889–5627). Due to copyright issues, OSHA cannot post consensus standards on the OSHA website or through *www.regulations.gov.*

List of Subjects

29 CFR Part 1910

COVID–19, Disease, Health, Health care, Health facilities, Incorporation by reference, Occupational safety and health, Public health, Quarantine, Reporting and recordkeeping requirements, Respirators, SARS–CoV–2, Telework, Vaccines, Viruses.

29 CFR Parts 1915, 1917, 1918, 1926, and 1928

COVID–19, Disease, Health, Health care, Health facilities, Occupational safety and health, Public health, Quarantine, Reporting and recordkeeping requirements, Respirators, SARS–CoV–2, Telework, Vaccines, Viruses.

Authority and Signature

James S. Frederick, Acting Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, authorized the preparation of this document pursuant to the following authorities: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order 8–2020 (85 FR 58393 (Sept. 18, 2020)); 29 CFR part 1911; and 5 U.S.C. 553.

James S. Frederick,

Acting Assistant Secretary of Labor for Occupational Safety and Health.

For the reasons set forth in the preamble, chapter XVII of title 29 of the Code of Federal Regulations is amended as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart U—COVID–19

■ 1. Revise the heading for Subpart U to read as set forth above.

■ 2. The authority citation for subpart U continues to read as follows:

Authority: 29 U.S.C. 653, 655, and 657; Secretary of Labor's Order No. 8–2020 (85 FR 58393); 29 CFR part 1911; and 5 U.S.C. 553.

■ 3. Add § 1910.501 to subpart U to read as follows:

§ 1910.501 Vaccination, testing, and face coverings.

(a) *Purpose.* This section is intended to establish minimum vaccination, vaccination verification, face covering, and testing requirements to address the grave danger of COVID–19 in the workplace, and to preempt inconsistent state and local requirements relating to these issues, including requirements that ban or limit employers' authority to require vaccination, face covering, or testing, regardless of the number of employees.

Note 1 to paragraph (a): This section establishes minimum requirements that employers must implement. Nothing in this section prevents employers from agreeing with workers and their representatives to additional measures not required by this section and this section does not supplant collective bargaining agreements or other collectively negotiated agreements in effect that may have negotiated terms that exceed the requirements herein. The National Labor Relations Act of 1935 (NLRA) protects the right of most private-sector employees to take collective action to improve their wages and working conditions.

(b) *Scope and application.* (1) This section covers all employers with a total of 100 or more employees at any time this section is in effect.

(2) The requirements of this section do not apply to:

(i) Workplaces covered under the Safer Federal Workforce Task Force COVID–19 Workplace Safety: Guidance for Federal Contractors and Subcontractors; or

(ii) Settings where any employee provides healthcare services or healthcare support services when subject to the requirements of § 1910.502.

(3) The requirements of this section do not apply to the employees of covered employers:

(i) Who do not report to a workplace where other individuals such as coworkers or customers are present;

(ii) While working from home; or

(iii) Who work exclusively outdoors.

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

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

COVID–19 (Coronavirus Disease 2019) means the disease caused by SARS–CoV–2 (severe acute respiratory syndrome coronavirus 2). For clarity and ease of reference, this section also uses the term ''COVID–19'' when describing exposures or potential exposures to SARS–CoV–2.

COVID–19 test means a test for SARS–CoV–2 that is:

(i) Cleared, approved, or authorized, including in an Emergency Use Authorization (EUA), by the FDA to detect current infection with the SARS–CoV–2 virus (*e.g.,* a viral test);

(ii) Administered in accordance with the authorized instructions; and

(iii) Not both self-administered and self-read unless observed by the employer or an authorized telehealth proctor. Examples of tests that satisfy this requirement include tests with specimens that are processed by a laboratory (including home or on-site collected specimens which are processed either individually or as pooled specimens), proctored over-the-counter tests, point of care tests, and tests where specimen collection and processing is either done or observed by an employer.

Face covering means a covering that:

(i)(A) completely covers the nose and mouth;

(B) Is made with two or more layers of a breathable fabric that is tightly woven (*i.e.,* fabrics that do not let light pass through when held up to a light source);

(C) Is secured to the head with ties, ear loops, or elastic bands that go behind the head. If gaiters are worn, they should have two layers of fabric or be folded to make two layers;

(D) Fits snugly over the nose, mouth, and chin with no large gaps on the outside of the face; and

(E) Is a solid piece of material without slits, exhalation valves, visible holes, punctures, or other openings.

(ii) This definition includes clear face coverings or cloth face coverings with a clear plastic panel that, despite the non-cloth material allowing light to pass through, otherwise meet this definition and which may be used to facilitate communication with people who are deaf or hard-of-hearing or others who need to see a speaker's mouth or facial expressions to understand speech or sign language respectively.

Facemask means a surgical, medical procedure, dental, or isolation mask that is FDA-cleared, authorized by an FDA EUA, or offered or distributed as

described in an FDA enforcement policy. Facemasks may also be referred to as ''medical procedure masks.''

Fully vaccinated means:

(i) A person's status 2 weeks after completing primary vaccination with a COVID–19 vaccine with, if applicable, at least the minimum recommended interval between doses in accordance with the approval, authorization, or listing that is:

(A) Approved or authorized for emergency use by the FDA;

(B) Listed for emergency use by the World Health Organization (WHO); or

(C) Administered as part of a clinical trial at a U.S. site, if the recipient is documented to have primary vaccination with the active (not placebo) COVID–19 vaccine candidate, for which vaccine efficacy has been independently confirmed (*e.g.,* by a data and safety monitoring board) or if the clinical trial participant at U.S. sites had received a COVID–19 vaccine that is neither approved nor authorized for use by FDA but is listed for emergency use by WHO; or

(ii) A person's status 2 weeks after receiving the second dose of any combination of two doses of a COVID–19 vaccine that is approved or authorized by the FDA, or listed as a two-dose series by the WHO (*i.e.,* a heterologous primary series of such vaccines, receiving doses of different COVID–19 vaccines as part of one primary series). The second dose of the series must not be received earlier than 17 days (21 days with a 4-day grace period) after the first dose.

Mandatory Vaccination Policy is an employer policy requiring each employee to be fully vaccinated. To meet this definition, the policy must require: Vaccination of all employees, including vaccination of all new employees as soon as practicable, other than those employees:

(i) For whom a vaccine is medically contraindicated;

(ii) For whom medical necessity requires a delay in vaccination; or

(iii) Who are legally entitled to a reasonable accommodation under federal civil rights laws because they have a disability or sincerely held religious beliefs, practices, or observances that conflict with the vaccination requirement.

Respirator means a type of personal protective equipment (PPE) that is certified by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84 or is authorized under an EUA by the FDA. Respirators protect against airborne hazards by removing specific air contaminants from the ambient (surrounding) air or by supplying breathable air from a safe source. Common types of respirators include filtering facepiece respirators (*e.g.,* N95), elastomeric respirators, and powered air purifying respirators (PAPRs). Face coverings, facemasks, and face shields are not respirators.

Workplace means a physical location (*e.g.,* fixed, mobile) where the employer's work or operations are performed. It does not include an employee's residence.

(d) *Employer policy on vaccination.* (1) The employer must establish, implement, and enforce a written mandatory vaccination policy.

(2) The employer is exempted from the requirement in paragraph (d)(1) of this section only if the employer establishes, implements, and enforces a written policy allowing any employee not subject to a mandatory vaccination policy to choose either to be fully vaccinated against COVID–19 or provide proof of regular testing for COVID–19 in accordance with paragraph (g) of this section and wear a face covering in accordance with paragraph (i) of this section.

Note 1 to paragraph (d): Under federal law, including the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964, workers may be entitled to a reasonable accommodation from their employer, absent undue hardship. If the worker requesting a reasonable accommodation cannot be vaccinated and/or wear a face covering because of a disability, as defined by the ADA, the worker may be entitled to a reasonable accommodation. In addition, if the vaccination, and/or testing for COVID–19, and/or wearing a face covering conflicts with a worker's sincerely held religious belief, practice or observance, the worker may be entitled to a reasonable accommodation. For more information about evaluating requests for reasonable accommodation for disability or sincerely held religious belief, employers should consult the Equal Employment Opportunity Commission's regulations, guidance, and technical assistance including at: *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.*

(e) *Determination of employee vaccination status.* (1) The employer must determine the vaccination status of each employee. This determination must include whether the employee is fully vaccinated.

(2) The employer must require each vaccinated employee to provide acceptable proof of vaccination status, including whether they are fully or partially vaccinated. Acceptable proof of vaccination status is:

(i) The record of immunization from a health care provider or pharmacy;

(ii) A copy of the COVID–19 Vaccination Record Card;

(iii) A copy of medical records documenting the vaccination;

(iv) A copy of immunization records from a public health, state, or tribal immunization information system; or

(v) A copy of any other official documentation that contains the type of vaccine administered, date(s) of administration, and the name of the health care professional(s) or clinic site(s) administering the vaccine(s);

(vi) In instances where an employee is unable to produce acceptable proof of vaccination under paragraphs (e)(2)(i) through (v) of this section, a signed and dated statement by the employee:

(A) Attesting to their vaccination status (fully vaccinated or partially vaccinated);

(B) Attesting that they have lost and are otherwise unable to produce proof required by this section; and

(C) Including the following language: ''I declare (or certify, verify, or state) that this statement about my vaccination status is true and accurate. I understand that knowingly providing false information regarding my vaccination status on this form may subject me to criminal penalties.''

Note 1 to paragraph (e)(2)(vi): An employee who attests to their vaccination status should, to the best of their recollection, include the following information in their attestation: The type of vaccine administered; date(s) of administration; and the name of the health care professional(s) or clinic site(s) administering the vaccine(s).

(3) Any employee who does not provide one of the acceptable forms of proof of vaccination status in paragraph (e)(2) of this section to the employer must be treated as not fully vaccinated for the purpose of this section.

(4) The employer must maintain a record of each employee's vaccination status and must preserve acceptable proof of vaccination for each employee who is fully or partially vaccinated. The employer must maintain a roster of each employee's vaccination status. These records and roster are considered to be employee medical records and must be maintained as such records in accordance with § 1910.1020 and must not be disclosed except as required or authorized by this section or other federal law. These records and roster are not subject to the retention requirements of § 1910.1020(d)(1)(i) but must be maintained and preserved while this section remains in effect.

(5) When an employer has ascertained employee vaccination status prior to the effective date of this section through another form of attestation or proof, and retained records of that ascertainment,

the employer is exempt from the requirements in paragraphs (e)(1) through (3) of this section only for each employee whose fully vaccinated status has been documented prior to the effective date of this section. For purposes of paragraph (e)(4) of this section, the employer's records of ascertainment of vaccination status for each such person constitute acceptable proof of vaccination.

(f) *Employer support for employee vaccination.* The employer must support COVID–19 vaccination as described in this paragraph.

(1) *Time for vaccination.* The employer must:

(i) Provide a reasonable amount of time to each employee for each of their primary vaccination dose(s); and

(ii) Provide up to 4 hours paid time, including travel time, at the employee's regular rate of pay for this purpose.

(2) *Time for recovery.* The employer must provide reasonable time and paid sick leave to recover from side effects experienced following any primary vaccination dose to each employee for each dose.

(g) *COVID–19 testing for employees who are not fully vaccinated.* (1) The employer must ensure that each employee who is not fully vaccinated complies with paragraph (g)(1)(i) or (ii) of this section:

(i) An employee who reports at least once every 7 days to a workplace where other individuals such as coworkers or customers are present:

(A) Must be tested for COVID–19 at least once every 7 days; and

(B) Must provide documentation of the most recent COVID–19 test result to the employer no later than the 7th day following the date on which the employee last provided a test result.

(ii) An employee who does not report during a period of 7 or more days to a workplace where other individuals such as coworkers or customers are present (*e.g.,* teleworking for two weeks prior to reporting to a workplace with others):

(A) Must be tested for COVID–19 within 7 days prior to returning to the workplace; and

(B) Must provide documentation of that test result to the employer upon return to the workplace.

Note 1 to paragraph (g)(1): This section does not require the employer to pay for any costs associated with testing; however employer payment for testing may be required by other laws, regulations, or collective bargaining agreements or other collectively negotiated agreements. This section also does not prohibit the employer from paying for costs associated with testing required by paragraph (g)(1) of this section.

(2) If an employee does not provide documentation of a COVID–19 test result as required by paragraph (g)(1) of this section, the employer must keep that employee removed from the workplace until the employee provides a test result.

(3) When an employee has received a positive COVID–19 test, or has been diagnosed with COVID–19 by a licensed healthcare provider, the employer must not require that employee to undergo COVID–19 testing as required under paragraph (g) of this section for 90 days following the date of their positive test or diagnosis.

(4) The employer must maintain a record of each test result provided by each employee under paragraph (g)(1) of this section or obtained during tests conducted by the employer. These records are considered to be employee medical records and must be maintained as such records in accordance with § 1910.1020 and must not be disclosed except as required or authorized by this section or other federal law. These records are not subject to the retention requirements of § 1910.1020(d)(1)(i) but must be maintained and preserved while this section remains in effect.

(h) *Employee notification to employer of a positive COVID–19 test and removal.* Regardless of COVID–19 vaccination status or any COVID–19 testing required under paragraph (g) of this section, the employer must:

(1) Require each employee to promptly notify the employer when they receive a positive COVID–19 test or are diagnosed with COVID–19 by a licensed healthcare provider; and

(2) Immediately remove from the workplace any employee who receives a positive COVID–19 test or is diagnosed with COVID–19 by a licensed healthcare provider and keep the employee removed until the employee:

(i) Receives a negative result on a COVID–19 nucleic acid amplification test (NAAT) following a positive result on a COVID–19 antigen test if the employee chooses to seek a NAAT test for confirmatory testing;

(ii) meets the return to work criteria in CDC's ''Isolation Guidance'' (incorporated by reference, § 1910.509); or

(iii) Receives a recommendation to return to work from a licensed healthcare provider.

Note 1 to paragraph (h)(2): This section does not require employers to provide paid time to any employee for removal as a result of a positive COVID–19 test or diagnosis of COVID–19; however, paid time may be required by other laws, regulations, or collective bargaining agreements or other collectively negotiated agreements.

(i) *Face coverings.* (1) The employer must ensure that each employee who is not fully vaccinated wears a face covering when indoors and when occupying a vehicle with another person for work purposes, except:

(i) When an employee is alone in a room with floor to ceiling walls and a closed door.

(ii) For a limited time while the employee is eating or drinking at the workplace or for identification purposes in compliance with safety and security requirements.

(iii) When an employee is wearing a respirator or facemask.

(iv) Where the employer can show that the use of face coverings is infeasible or creates a greater hazard that would excuse compliance with this paragraph (*e.g.,* when it is important to see the employee's mouth for reasons related to their job duties, when the work requires the use of the employee's uncovered mouth, or when the use of a face covering presents a risk of serious injury or death to the employee).

(2) The employer must ensure that any face covering required to be worn by this section:

(i) Is worn by the employee to fully cover the employee's nose and mouth; and

(ii) Is replaced when wet, soiled, or damaged (*e.g.,* is ripped, has holes, or has broken ear loops).

(3) The employer must not prevent any employee from voluntarily wearing a face covering or facemask unless the employer can demonstrate that doing so would create a hazard of serious injury or death, such as interfering with the safe operation of equipment.

(4) The employer must permit the employee to wear a respirator instead of a face covering whether required or not. In addition, the employer may provide respirators to the employee, even if not required. In such circumstances, the employer must also comply with § 1910.504.

(5) The employer must not prohibit customers or visitors from wearing face coverings.

Note 1 to paragraph (i)(5): Nothing in this section precludes employers from requiring customers or visitors to wear face coverings.

Note 1 to paragraph (i): Face shields may be worn in addition to face coverings to prevent them from getting wet and soiled.

Note 2 to paragraph (i): This section does not require the employer to pay for any costs associated with face coverings; however employer payment for face coverings may be required by other laws, regulations, or collective bargaining agreements or other collectively negotiated agreements. This section also does not prohibit the employer

from paying for costs associated with face coverings required by this section.

(j) *Information provided to employees.* The employer must inform each employee, in a language and at a literacy level the employee understands, about:

(1) The requirements of this section as well as any employer policies and procedures established to implement this section;

(2) COVID–19 vaccine efficacy, safety, and the benefits of being vaccinated, by providing the document, ''Key Things to Know About COVID–19 Vaccines,'' available at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/keythingstoknow.html;*

(3) The requirements of 29 CFR 1904.35(b)(1)(iv), which prohibits the employer from discharging or in any manner discriminating against an employee for reporting a work-related injuries or illness, and section 11(c) of the OSH Act, which prohibits the employer from discriminating against an employee for exercising rights under, or as a result of actions that are required by, this section. Section 11(c) also protects the employee from retaliation for filing an occupational safety or health complaint, reporting a work-related injuries or illness, or otherwise exercising any rights afforded by the OSH Act; and

(4) The prohibitions of 18 U.S.C. 1001 and of section 17(g) of the OSH Act, which provide for criminal penalties associated with knowingly supplying false statements or documentation.

(k) *Reporting COVID–19 fatalities and hospitalizations to OSHA.* (1) The employer must report to OSHA:

(i) Each work-related COVID–19 fatality within 8 hours of the employer learning about the fatality.

(ii) Each work-related COVID–19 in-patient hospitalization within 24 hours of the employer learning about the in-patient hospitalization.

(2) When reporting COVID–19 fatalities and in-patient hospitalizations to OSHA in accordance with paragraph (j)(1) of this section, the employer must follow the requirements in 29 CFR part 1904.39, except for 29 CFR part 1904.39(a)(1) and (2) and (b)(6).

(l) *Availability of records.* (1) By the end of the next business day after a request, the employer must make available, for examination and copying, the individual COVID–19 vaccine documentation and any COVID–19 test results for a particular employee to that employee and to anyone having written authorized consent of that employee.

(2) By the end of the next business day after a request by an employee or an employee representative, the employer must make available to the requester the aggregate number of fully vaccinated employees at a workplace along with the total number of employees at that workplace.

(3) The employer must provide to the Assistant Secretary for examination and copying:

(i) Within 4 business hours of a request, the employer's written policy required by paragraph (d) of this section, and the aggregate numbers described in paragraph (l)(2) of this section; and

(ii) By the end of the next business day after a request, all other records and other documents required to be maintained by this section.

(m) *Dates—(1) Effective date.* This section is effective as of November 5, 2021.

(2) *Compliance dates.* (i) Employers must comply with all requirements of this section, except for requirements in paragraph (g) of this section, by December 6, 2021.

(ii) Employers must comply with the requirements of this section in paragraph (g) by January 4, 2022, but employees who have completed the entire primary vaccination by that date do not have to be tested, even if they have not yet completed the 2-week waiting period.

■ 4. Amend § 1910.504 by revising paragraph (a) to read as follows:

§ 1910.504 Mini Respiratory Protection Program.

(a) *Scope and application.* This section applies only to respirator use in accordance with §§ 1910.501(i)(4) and 1910.502(f)(4).

* * * * *

■ 5. Republish § 1910.505 to read as follows:

§ 1910.505 Severability.

Each section of this subpart U, and each provision within those sections, is separate and severable from the other sections and provisions. If any provision of this subpart is held to be invalid or unenforceable on its face, or as applied to any person, entity, or circumstance, or is stayed or enjoined, that provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this subpart and shall not affect the remainder of the subpart.

■ 6. Amend § 1910.509 by revising paragraph (b)(5) to read as follows:

§ 1910.509 Incorporation by reference.

* * * * *

(b) * * *

(5) Isolation Guidance. COVID–19: Isolation If You Are Sick; Separate yourself from others if you have COVID–19, updated February 18, 2021, IBR approved for §§ 1910.501(h) and 1910.502(l).

* * * * *

PART 1915—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR SHIPYARD EMPLOYMENT

■ 7. The authority citation for part 1915 is revised to read as follows:

Authority: 33 U.S.C. 941; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754); 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), 1–2012 (77 FR 3912), or 8–2020 (85 FR 58393); 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

Subpart Z—Toxic and Hazardous Substances

■ 8. Add § 1915.1501 to subpart Z to read as follows:

§ 1915.1501 COVID–19.

The requirements applicable to shipyard employment under this section are identical to those set forth at 29 CFR 1910.501.

PART 1917—MARINE TERMINALS

■ 9. The authority citation for part 1917 is revised to read as follows:

Authority: 33 U.S.C. 941; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), 1–2012 (77 FR 3912), or 8–2020 (85 FR 58393), as applicable; and 29 CFR part 1911.

Sections 1917.28 and 1917.31 also issued under 5 U.S.C. 553.

Section 1917.29 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 553.

Subpart B—Marine Terminal Operations

■ 10. Add § 1917.31 to subpart B to read as follows:

§ 1917.31 COVID–19.

The requirements applicable to marine terminal work under this section are identical to those set forth at 29 CFR 1910.501.

PART 1918—SAFETY AND HEALTH REGULATIONS FOR LONGSHORING

■ 11. The authority citation for part 1918 is revised to read as follows:

Authority: 33 U.S.C. 941; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), 1–2012 (77 FR 3912), or 8–2020 (85 FR 58393), as applicable; and 29 CFR 1911.

Sections 1918.90 and 1918.110 also issued under 5 U.S.C. 553.

Section 1918.100 also issued under 49 U.S.C. 5101 et seq. and 5 U.S.C. 553.

■ 12. Add subpart K to part 1918 to read as follows:

Subpart K—COVID–19.

Sec.
1918.107–1918.109 [Reserved]
1918.110 COVID–19.
1918.107 through 1918.109 [Reserved]

§ 1918.110 COVID–19.

The requirements applicable to longshoring work under this section are identical to those set forth at 29 CFR 1910.501.

PART 1926—SAFETY AND HEALTH REGULATIONS FOR CONSTRUCTION

■ 13. The authority citation for part 1926 is revised to read as follows:

Authority: 40 U.S.C. 3704; 29 U.S.C. 653, 655, and 657; and Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31159), 4–2010 (75 FR 55355), 1–2012 (77 FR 3912), or 8–2020 (85 FR 58393), as applicable; and 29 CFR part 1911.

Sections 1926.58, 1926.59, 1926.60, and 1926.65 also issued under 5 U.S.C. 553 and 29 CFR part 1911.

Section 1926.61 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 553.

Section 1926.62 also issued under sec. 1031, Public Law 102–550, 106 Stat. 3672 (42 U.S.C. 4853).

Section 1926.65 also issued under sec. 126, Public Law 99–499, 100 Stat. 1614 (reprinted at 29 U.S.C.A. 655 Note) and 5 U.S.C. 553.

Subpart D—Occupational Health and Environmental Controls

■ 14. Add § 1926.58 to read as follows:

§ 1926.58 COVID–19.

The requirements applicable to construction work under this section are identical to those set forth at 29 CFR 1910.501 Subpart U.

PART 1928—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR AGRICULTURE

■ 15. The authority citation for part 1928 is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 4–2010 (75 FR 55355), or 8–2020 (85 FR 58393), as applicable; and 29 CFR 1911.

Section 1928.21 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 553.

Subpart B—Applicability of Standards

■ 16. Amend § 1928.21 by adding paragraph (a)(8) to read as follows:

§ 1928.21 Applicable standards in 29 CFR part 1910.

(a) * * *

(8) COVID–19—§ 1910.501, but only with respect to—

(i) Agricultural establishments where eleven (11) or more employees are engaged on any given day in hand-labor operations in the field; and

(ii) Agricultural establishments that maintain a temporary labor camp, regardless of how many employees are engaged on any given day in hand-labor operations in the field.

* * * * *

[FR Doc. 2021–23643 Filed 11–4–21; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416, 418, 441, 460, 482, 483, 484, 485, 486, 491 and 494

[CMS–3415–IFC]

RIN 0938–AU75

Medicare and Medicaid Programs; Omnibus COVID–19 Health Care Staff Vaccination

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period revises the requirements that most Medicare- and Medicaid-certified providers and suppliers must meet to participate in the Medicare and Medicaid programs. These changes are necessary to help protect the health and safety of residents, clients, patients, PACE participants, and staff, and reflect lessons learned to date as a result of the COVID–19 public health emergency. The revisions to the requirements establish COVID–19 vaccination requirements for staff at the included Medicare- and Medicaid-certified providers and suppliers.

DATES:

Effective date: These regulations are effective on November 5, 2021.

Implementation dates: The regulations included in Phase 1 [42 CFR 416.51(c) through (c)(3)(i) and (c)(3)(iii) through (x), 418.60(d) through (d)(3)(i) and (d)(3)(iii) through (x), 441.151(c) through (c)(3)(i) and (c)(3)(iii) through (x), 460.74(d) through (d)(3)(i) and (d)(3)(iii) through (x), 482.42(g) through (g)(3)(i) and (g)(3)(iii) through (x), 483.80(d)(3)(v) and 483.80(i) through (i)(3)(i) and (i)(3)(iii) through (x), 483.430(f) through (f)(3)(i) and (f)(3)(iii) through (x), 483.460(a)(4)(v), 484.70(d) through (d)(3)(i) and (d)(3)(iii) through (x), 485.58(d)(4), 485.70(n) through (n)(3)(i) and (n)(3)(iii) through (x), 485.640(f) through (f)(3)(i) and (f)(3)(iii) through (x), 485.725(f) through (f)(3)(i) through (f)(3)(iii) through (x), 485.904(c) through (c)(3)(i) and (c)(3)(iii) through (x), 486.525(c) through (c)(3)(i) and (c)(3)(iii) through (x), 491.8(d) through (d)(3)(i) and (d)(3)(iii) through (x), 494.30(b) through (b)((3)(i) and (b)(3)(iii) through (x) must be implemented by December 6, 2021.

The regulations included in Phase 2 [42 CFR 416.51(c)(3)(ii), 418.60(d)(3)(ii), 441.151(c)(3)(ii), 460.74(d)(3)(ii), 482.42(g)(3)(ii), 483.80(i)(3)(ii), 483.430(f)(3)(ii), 484.70(d)(3)(ii), 485.70(n)(3)(ii), 485.640(f)(3)(ii), 485.725(f)(3)(ii), 485.904(c)(3)(ii), 486.525(c)(3)(ii), 491.8(d)(3)(ii), 494.30(b)(3)(ii)] must be implemented by January 4, 2022. Staff who have completed a primary vaccination series by this date are considered to have met these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 4, 2022.

ADDRESSES: In commenting, please refer to file code CMS–3415–IFC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3415–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3415–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: CMS Office of Communications, Department of Health and Human Services; email *press@cms.hhs.gov.*

For technical inquiries: Contact CMS Center for Clinical Standards and Quality, Department of Health and Human Services, (410) 786–6633.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

The Centers for Medicare & Medicaid Services (CMS) establishes health and safety standards, known as the Conditions of Participation, Conditions for Coverage, or Requirements for Participation for 21 types of providers and suppliers, ranging from hospitals to hospices and rural health clinics to long term care facilities (including skilled nursing facilities and nursing facilities, collectively known as nursing homes). Most of these providers and suppliers are regulated by this interim final rule with comment period (IFC). Specifically, this IFC directly regulates the following providers and suppliers, listed in the numerical order of the relevant CFR sections being revised in this rule:

- Ambulatory Surgical Centers (ASCs) (§ 416.51)
- Hospices (§ 418.60)
- Psychiatric residential treatment facilities (PRTFs) (§ 441.151)
- Programs of All-Inclusive Care for the Elderly (PACE) (§ 460.74)
- Hospitals (acute care hospitals, psychiatric hospitals, hospital swing beds, long term care hospitals, children's hospitals, transplant centers, cancer hospitals, and rehabilitation hospitals/inpatient rehabilitation facilities) (§ 482.42)
- Long Term Care (LTC) Facilities, including Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs), generally referred to as nursing homes (§ 483.80)
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs–IID) (§ 483.430)
- Home Health Agencies (HHAs) (§ 484.70)
- Comprehensive Outpatient Rehabilitation Facilities (CORFs) (§§ 485.58 and 485.70)
- Critical Access Hospitals (CAHs) (§ 485.640)
- Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services (§ 485.725)
- Community Mental Health Centers (CMHCs) (§ 485.904)
- Home Infusion Therapy (HIT) suppliers (§ 486.525)
- Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs) (§ 491.8)
- End-Stage Renal Disease (ESRD) Facilities (§ 494.30)

This IFC directly applies only to the Medicare- and Medicaid-certified providers and suppliers listed above. It does not directly apply to other health care entities, such as physician offices, that are not regulated by CMS. Most states have separate licensing requirements for health care staff and health care providers that would be applicable to physician office staff and other staff in small health care entities that are not subject to vaccination requirements under this IFC. We have not included requirements for Organ Procurement Organizations or Portable X-Ray suppliers, as these only provide services under contract to other health care entities and would thus be indirectly subject to the vaccination requirements of this rule, as discussed in section II.A.1. of this rule. We note that entities not covered by this rule may still be subject to other State or Federal COVID–19 vaccination requirements, such as those issued by Occupational Safety and Health Administration (OSHA) for certain employers.

Currently, the United States (U.S.) is responding to a public health emergency (PHE) of respiratory disease caused by a novel coronavirus that has now been detected in more than 190 countries internationally, all 50 States, the District of Columbia, and all U.S. territories. The virus has been named ''severe acute respiratory syndrome coronavirus 2'' (SARS–CoV–2), and the disease it causes has been named ''coronavirus disease 2019'' (COVID–19). On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of International Concern.'' On January 31, 2020, pursuant to section 319 of the Public Health Service Act (PHSA) (42 U.S.C. 247d), the Secretary of the Department of Health and Human Services (Secretary) determined that a PHE exists for the U.S. (hereafter referred to as the PHE for COVID–19). On March 11, 2020, the WHO publicly declared COVID–19 a pandemic. On March 13, 2020, the President of the United States declared the COVID–19 pandemic a national emergency. The January 31, 2020 determination that a PHE for COVID–19 exists and has existed since January 27, 2020, lasted for 90 days, and was renewed on April 21, 2020; July 23, 2020; October 2, 2020; January 7, 2021; April 15, 2021; July 19, 2021; and October 18, 2021. Pursuant to section 319 of the PHSA, the determination that a PHE continues to exist may be renewed at the end of each 90-day period.[1]

COVID–19 has had significant negative health effects—on individuals, communities, and the nation as a whole. Consequences for individuals who have COVID–19 include morbidity, hospitalization, mortality, and post-COVID conditions (also known as long COVID). As of mid-October 2021, over 44 million COVID–19 cases, 3 million new COVID–19 related hospitalizations, and 720,000 COVID–19 deaths have been reported in the U.S.[2] Indeed, COVID–19 has overtaken the 1918 influenza pandemic as the deadliest disease in American history.[3]

[1] *https://www.phe.gov/emergency/events/COVID19/Pages/2019-Public-Health-and-Medical-Emergency-Declarations-and-Waivers.aspx.*

[2] *https://covid.cdc.gov/covid-data-tracker#datatracker-home.*

[3] *https://www.statnews.com/2021/09/20/covid-19-set-to-overtake-1918-spanish-flu-as-deadliest-disease-in-american-history.*

Given recent estimates of undiagnosed infections and under-reported deaths, these figures likely underestimate the full impact.[4] In addition, these figures fail to capture the significant, detrimental effects of post-acute illness, including nervous system and neurocognitive disorders, cardiovascular disorders, gastrointestinal disorders, and signs and symptoms related to poor general well-being, including malaise, fatigue, musculoskeletal pain, and reduced quality of life. Recent estimates suggest more than half of COVID–19 survivors experienced post-acute sequelae of COVID–19 6 months after recovery.[5] The individual and public health ramifications of COVID–19 also extend beyond the direct effects of COVID–19 infections. Several studies have demonstrated significant mortality increases in 2020, beyond those attributable to COVID–19 deaths. In some percentage, this could be a problem of misattribution (for example, the cause of death was indicated as ''heart disease'' but in fact the true cause was undiagnosed COVID–19), but some proportion are also believed to reflect increases in other causes of death that are sensitive to decreased access to care and/or increased mental/emotional strain. One paper quantifies the net impact (direct and indirect effects) of the pandemic on the U.S. population during 2020 using three metrics: excess deaths, life expectancy, and total years of life lost. The findings indicate there were 375,235 excess deaths, with 83 percent attributable to direct, and 17 percent attributable to indirect effects of COVID–19. The decrease in life expectancy was 1.67 years, translating to a reversion of 14 years in historical life expectancy gains. Total years of life lost in 2020 was 7,362,555 across the U.S. (73 percent directly attributable, 27 percent indirectly attributable to COVID–19), with considerable heterogeneity at the individual State level.[6]

One analysis published in February 2021 found that Black and Latino Americans have experienced a disproportionate burden of COVID–19 morbidity and mortality, reflecting persistent structural inequalities that increase risk of exposure to COVID–19 and mortality risk for those infected. The authors projected that COVID–19 would reduce U.S. life expectancy in 2020 by 1.13 years. Furthermore, the estimated reduction for Black and Latino populations is 3–4 times the estimate for the White population, reversing over 10 years of progress in reducing the gaps in life expectancy between Black and White populations and reducing the Latino mortality advantage by over 70 percent. The study further expects that reductions in life expectancy may persist because of continued COVID–19 mortality and term health, social, and economic impacts of the pandemic.[7] Because SARS–CoV–2, the virus that causes COVID–19 disease, is highly transmissible,[8] Centers for Disease Control and Prevention (CDC) has recommended, and CMS reiterated, that health care providers and suppliers implement robust infection prevention and control practices, including source control measures, physical distancing, universal use of personal protective equipment (PPE), SARS–CoV–2 testing, environmental controls, and patient isolation or quarantine.[9] [10] [11] [12] Available evidence suggests these infection prevention and control practices have been highly effective when implemented correctly and consistently.[13] [14]

Studies have also shown, however, that consistent adherence to recommended infection prevention and control practices can prove challenging—and those lapses can place patients in jeopardy.[15] [16] [17] [18] A retrospective analysis from England found up to 1 in 6 SARS–CoV–2 infections among hospitalized patients with COVID–19 in England during the first 6 months of the pandemic could be attributed to healthcare-associated transmission.[19] In outbreaks reported from acute care settings in the U.S. following implementation of universal masking, unmasked exposures to other health care workers were frequently implicated.[20] A retrospective cohort study of health care staff behaviors, exposures, and cases between June and December 2020 in a large health system found more employees were exposed via coworkers than patients—and secondary cases among employees typically followed unmasked interactions with infected colleagues (for example, convening in breakrooms without proper source control).[21] The same study found that cases of health care worker infection associated with patient exposures could often be attributed to failure to adhere to PPE requirements (for example, eye protection). Past experience with influenza, and available evidence, suggest that vaccination of health care staff offers a critical layer of protection against healthcare-associated COVID–19 (HA–COVID–19). For example, evidence has shown that influenza vaccination of health care staff is associated with declines in nosocomial influenza in hospitalized patients,[22] [23] [24] and among nursing home residents.[25] [26] [27] [28] [29] [30] [31]

[4] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8354557/.*

[5] *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2784918.*

[6] *https://pubmed.ncbi.nlm.nih.gov/34469474/.*

[7] Andrasfay, T., & Goldman, N. (2021). Reductions in 2020 US life expectancy due to COVID–19 and the disproportionate impact on the Black and Latino populations. Proceedings of the National Academy of Sciences of the United States of America, 118(5), e2014746118. *https://doi.org/10.1073/pnas.2014746118* Accessed 10/17/2021.

[8] *https://www.npr.org/sections/goatsandsoda/2021/08/11/1026190062/covid-delta-variant-transmission-cdc-chickenpox.*

[9] *https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.*

[10] *https://www.cms.gov/files/document/qso-21-08-nltc.pdf.*

[11] *https://www.cms.gov/files/document/qso-21-07-psych-hospital-prtf-icf-iid.pdf.*

[12] *https://www.cms.gov/files/document/qso-20-38-nh-revised.pdf.*

[13] *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2770287.*

[14] *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2777317.*

[15] *https://www.pnas.org/content/pnas/118/1/e2015455118.full.pdf.*

[16] *https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2782430.*

[17] *https://www.medrxiv.org/content/10.1101/2021.09.08.21263057v1.*

[18] *https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003816.*

[19] *https://www.medrxiv.org/content/10.1101/2021.02.16.21251625v1.*

[20] *https://jamanetwork.com/journals/jama/fullarticle/2773128.*

[21] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8349432/.*

[22] Weinstock DM, Eagan J, Malak SA, et al. Control of influenza A on a bone marrow transplant unit. *Infect Control Hosp Epidemiol.* 2000; 21:730–732.

[23] Salgado CD, Giannetta ET, Hayden FG, Farr BM. Preventing nosocomial influenza by improving the vaccine acceptance rate of clinicians. *Infect Control Hosp Epidemiol* 2004; 25:923–928.

[24] *https://pubmed.ncbi.nlm.nih.gov/31384750/.*

[25] Hayward AC, Harling R, Wetten S, et al. Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. *BMJ* 2006; 333: 1241–1246.

[26] Potter J, Stott DJ, Roberts MA, et al. Influenza vaccination of healthcare workers in long-term-care hospitals reduces the mortality of elderly patients. J *Infect Dis.* 1997; 175:1–6.

[27] Thomas RE, Jefferson TO, Demicheli V, et al. Influenza vaccination for health-care workers who work with elderly people in institutions: a systematic review. *Lancet Infect Dis.* 2006; 6:273–279.

[28] Van den Dool C, Bonten MJM, Hak E, Heijne JCM, Wallinga J. The effects of influenza vaccination of health care workers in nursing homes: insights from a mathematical model. *PLoS Medicine.* 2008; 5:1453–1460.

Lemaitre M, Meret T, Rothan-Tondeur M, et al. Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster-randomized trial. *J Am Geriatr Soc.* 2009; 57:1580–1586.

[29] Lemaitre M, Meret T, Rothan-Tondeur M, et al. Effect of influenza vaccination of nursing home staff

Continued

As a result, CDC, the Society for Healthcare Epidemiology of America, and others recommend—and a number of states require— annual influenza vaccination for health care staff.[32] [33] [34]

In addition to preventing morbidity and mortality associated with COVID–19, currently approved or authorized vaccines also demonstrate effectiveness against asymptomatic SARS–CoV–2 infection. A recent study of health care workers in 8 states found that, between December 14, 2020 through August 14, 2021, full vaccination with COVID–19 vaccines was 80 percent effective in preventing RT–PCR–confirmed SARS–CoV–2 infection among frontline workers.[35] Emerging evidence also suggests that vaccinated people who become infected with the SARS–CoV–2 Delta variant have potential to be less infectious than infected unvaccinated people, thus decreasing transmission risk.[36] For example, in a study of breakthrough infections among health care workers in the Netherlands, SARS–CoV–2 infectious virus shedding was lower among vaccinated individuals with breakthrough infections than among unvaccinated individuals with primary infections.[37] Fewer infected staff and lower transmissibility equates to fewer opportunities for transmission to patients, and emerging evidence indicates this is the case. The best data come from long term care facilities, as early implementation of national reporting requirements have resulted in a comprehensive, longitudinal, high quality data set. Data from CDC's National Healthcare Safety Network (NHSN) have shown that case rates among LTC facility residents are higher in facilities with lower vaccination coverage among staff; specifically, residents of LTC facilities in which vaccination coverage of staff is 75 percent or lower experience higher rates of preventable COVID–19.[38] Several articles published in CDC's Morbidity and Mortality Weekly Reports (MMWRs) regarding nursing home outbreaks have also linked the spread of COVID–19 infection to unvaccinated health care workers and stressed that maintaining a high vaccination rate is important for reducing transmission.[39] [40] [41]

There is also some published evidence from other settings that suggest similar dynamics can be expected in other health care delivery settings. For example, a recent analysis from Yale New Haven Hospital (YNHH) found health care units with at least 1 inpatient case of HA–COVID–19 had lower staff vaccination rates.[42] Similarly, a small study in Israel demonstrated that transmission of COVID–19 was linked to unvaccinated persons. In 37 cases, patients for whom data were available regarding the source of infection, the suspected source was an unvaccinated person; in 21 patients (57 percent), this person was a household member; in 11 cases (30 percent), the suspected source was an unvaccinated fellow health care worker or patient.[43] While similarly comprehensive data are not available for all Medicare- and Medicaid-certified provider types, the available evidence for ongoing healthcare-associated COVID–19 transmission risk is sufficiently alarming in and of itself to compel CMS to take action.

The threats that unvaccinated staff pose to patients are not, however, limited to SARS–CoV–2 transmission. Unvaccinated staff jeopardize patient access to recommended medical care and services, and these additional risks to patient health and safety further warrant CMS action.

Fear of exposure to and infection with COVID–19 from unvaccinated health care staff can lead patients to themselves forgo seeking medically necessary care. In a small but informative qualitative study of 33 home health care workers in New York City, one of the key themes to emerge from interviews with those workers was a keen recognition that ''providing care to patients placed them in a unique position with respect to COVID–19 transmission. They worried . . . about transmitting the virus to [their clients].'' They also noted that care for home bound clients might involve other health care staff, and they worried about ''transmitting COVID–19 . . . to one another.'' [44]

Anecdotal evidence suggests health care consumers have drawn similar conclusions—and this, too, has implications for overall health and welfare in health care settings. For example, CMS has received anecdotal reports suggesting individuals in care are refusing care from unvaccinated staff, limiting the extent to which providers and suppliers can effectively meet the health care needs of their patients and residents. Further, nationwide there are reports of individuals avoiding or forgoing health care due to fears of contracting COVID–19 from health care workers.[45] [46] [47] While avoidance of necessary care appears to have abated somewhat since the first months of the COVID–19 pandemic, it remains an area of concern for many individuals.[48] [49] Because

on mortality of residents: a cluster-randomized trial. *J Am Geriatr Soc.* 2009; 57:1580–1586.

Van den Dool C, Bonten MJM, Hak E, Heijne JCM, Wallinga J. The effects of influenza vaccination of health care workers in nursing homes: insights from a mathematical model. *PLoS Medicine.* 2008; 5:1453–1460.

[30] Oshitani H, Saito R, Seiki N, et al. Influenza vaccination levels and influenza-like illness in long-term–care facilities for elderly people in Niigata, Japan, during an influenza A (H3N2) epidemic. *Infect Control Hosp Epidemiol.* 2000; 21:728–730.

[31] *https://pubmed.ncbi.nlm.nih.gov/31384750/.*

[32] *https://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm.*

[33] *https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/revised-shea-position-paper-influenza-vaccination-of-healthcare-personnel/E83D4D87FBBBD80C66A2A4926D00F4B8.*

[34] *https://www.cdc.gov/phlp/publications/topic/vaccinationlaws.html.*

[35] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm?s_cid=mm7034e4_w.*

[36] *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html#ref43.*

[37] *https://www.medrxiv.org/content/10.1101/2021.08.20.21262158v1.full.pdf.*

[38] *https://emergency.cdc.gov/han/2021/han00447.asp.*

[39] COVID–19 Outbreak Associated with a SARS–CoV–2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program — Kentucky, March 2021.'' April 21, 2021. Available at *https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e2.htm.*

[40] Postvaccination SARS–CoV–2 Infections Among Skilled Nursing Facility Residents and Staff Members — Chicago, Illinois, December 2020–March 2021.'' April 30, 2021. Available at *https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e1.htm.*

[41] Effectiveness of the Pfizer-BioNTech COVID–19 Vaccine Among Residents of Two Skilled Nursing Facilities Experiencing COVID–19 Outbreaks — Connecticut, December 2020–February 2021.'' March 19, 2021. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7011e3.htm.*

[42] Roberts, S., Aniskiewicz, M., Choi, S., Pettker, C., & Martinello, R. (2021). Correlation of healthcare worker vaccination on inpatient healthcare-associated COVID–19. Infection Control & Hospital Epidemiology, 1–6. Doi:10.1017/ice.2021.414.

[43] Moriah Bergwerk, M.B., B.S., Tal Gonen, B.A., Yaniv Lustig, Ph.D., Sharon Amit, M.D., Marc Lipsitch, Ph.D., Carmit Cohen, Ph.D., Michal Mandelboim, Ph.D., Einav Gal Levin, M.D., Carmit Rubin, N.D., Victoria Indenbaum, Ph.D., Ilana Tal, R.N., Ph.D., Malka Zavitan, R.N., M.A., et al. Covid–19 Breakthrough Infections in Vaccinated Health Care Workers. N Engl J Med 2021; 385:1474–1484. DOI: 10.1056/NEJMoa2109072. *https://www.nejm.org/doi/full/10.1056/NEJMoa2109072.*

[44] *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2769096*).

[45] J Anxiety Disord. 2020 Oct; 75: 102289. Published online 2020 Aug 19. Doi: 10.1016/j.janxdis.2020.102289

[46] *https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6936a4-H.pdf.*

[47] *https://www.nahc.org/wp-content/uploads/2020/03/NATIONAL-SURVEY-SHOWS-HOME-HEALTH-CARE-ON-THE-FRONTLINES-OF-COVID-19-AND-CONTINUES-TO-BE-IN-A-FRAGILE-FINANCIAL-STATE.pdf.*

[48] *https://www.urban.org/sites/default/files/publication/103651/delayed-and-forgone-health-care-for-nonelderly-adults-during-the-covid-19-pandemic_1.pdf.*

[49] Gale R, Eberlein S, Fuller G, Khalil C, Almario CV, Spiegel BM. Public Perspectives on Decisions About Emergency Care Seeking for Care Unrelated

unvaccinated staff are at greater risk for infection, they also present a threat to health care operations—absenteeism due to COVID–19-related exposures or illness can create staffing shortages that disrupt patient access to recommended care. Data suggest the current surge in COVID–19 cases associated with emergence of the Delta variant has exacerbated health care staffing shortages. For example, 1 in 5 hospitals report that they are currently experiencing a critical staffing shortage.[50] Through the week ending September 19, 2021, approximately 23 percent of LTC facilities reported a shortage in nursing aides; 21 percent reported a shortage of nurses; and 10 to 12 percent reported shortages in other clinical and non-clinical staff categories.[51] And while some studies suggest overall staffing levels (as defined by nurse hours per resident day) have been relatively stable, this appears to be associated with concurrent decreases in patient demand (for example, resident census in nursing homes)—decreases that have ramifications for patient access to recommended and medically appropriate services.[52] [53] Over half (58 percent) of nursing homes participating in a recent survey conducted by the American Health Care Association and National Center for Assisted Living (AHCA/NCAL) indicated that they are limiting new admissions due to staffing shortages.[54] Similarly, hospital administrators responding to an OIG pulse survey conducted during February 22–26, 2021, reported difficulty discharging COVID–19 patients to post-acute facilities (for example, nursing homes, rehabilitation hospitals, and hospice facilities) following the acute stage of the patient's illness. These delays in discharge affected available bed space throughout the hospital (for example, creating bottlenecks in ICUs and EDs) and delayed patient access to specialized post-acute care (such as rehabilitation).[55] The drivers of this staffing crisis are multi-factorial. They include: Longstanding shortages in certain fields and professions; prolonged physical, mental, and emotional stress and trauma associated with responding to the ongoing PHE; and competing personal or professional obligations (such as child care) or opportunities (for example, new careers). But illnesses and deaths associated with COVID–19 are exacerbating staffing shortages across the health care system. Over half a million COVID–19 cases and 1,900 deaths among health care staff have been reported to CDC since the start of the PHE.[56] When submitting case-level COVID–19 reports, State and territorial jurisdictions may identify whether individuals are or are not health care workers. Since health care worker status has only been reported for a minority of cases (approximately 18 percent), these numbers are likely gross underestimates of true burden in this population. COVID–19 case rates among staff have also grown in tandem with broader national incidence trends since the emergence of the Delta variant. For example, as of mid-September 2021, COVID–19 cases among LTC facility and ESRD facility staff have increased by over 1400 percent and 850 percent, respectively, since their lows in June 2021.[57] Similarly, the number of cases among staff for whom case-level data were reported by State and territorial jurisdictions to CDC increased by nearly 600 percent between June and August 2021.[58] Vaccination is thus a powerful tool for protecting health and safety of patients, and, with the emergence and spread of the highly transmissible Delta variant, it has been an increasingly critical one to address the extraordinary strain the COVID–19 pandemic continues to place on the U.S. health system. While COVID–19 cases, hospitalizations, and deaths declined over the first 6 months of 2021, the emergence of the Delta variant reversed these trends.[59] Between late June 2021 and September 2021, daily cases of COVID–19 increased over 1200 percent; new hospital admissions, over 600 percent; and daily deaths, by nearly 800 percent.[60] Available data also continue to suggest that the majority of COVID–19 cases and hospitalizations are occurring among individuals who are not fully vaccinated. In a recent study of reported COVID–19 cases, hospitalizations, and deaths in 13 U.S. jurisdictions that routinely link case surveillance and immunization registry data, CDC found that unvaccinated individuals accounted for over 85 percent of all hospitalizations in the period between June and July 2021, when Delta became the predominant circulating variant.[61]

Unfortunately, health care staff vaccination rates remain too low in too many health care facilities and regions. For example, national COVID–19 vaccination rates for LTC facility, hospital, and ESRD facility staff are 67 percent, 64 percent, and 60 percent, respectively. Moreover, these averages obscure sizable regional differences. LTC facility staff vaccination rates range from lows of 56 percent to highs of over 90 percent, depending upon the State. Similar patterns hold for ESRD facility and hospital staff.[62] [63] [64] Given slow but steady increases in vaccination rates among staff working in these settings over time,[65] widespread availability of vaccines, and targeted efforts to facilitate vaccine access like the Federal Retail Pharmacy program,[66] vaccine hesitancy,[67] rather than other factors (for example, staff turnover) is likely to account for suboptimal staff vaccination rates.

While a significant number of health care staff have been infected with SARS–CoV–2,[68] evidence indicates their infection-induced immunity, also called ''natural immunity,'' is not equivalent to receiving the COVID–19 vaccine. Available evidence indicates that COVID–19 vaccines offer better protection than infection-induced immunity alone and that vaccines, even after prior infection, help prevent

to COVID–19 During the COVID–19 Pandemic. JAMA Netw Open. 2021;4(8):e2120940. Doi:10.1001/jamanetworkopen.2021.20940.

[50] Analysis of data submitted by hospitals through HHS Protect; accessed September 20, 2021.

[51] Data reported through CDC's NHSN.

[52] *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.02351.*

[53] *https://www.npr.org/sections/health-shots/2021/10/14/1043414558/with-hospitals-crowded-from-covid-1-in-5-american-families-delays-health-care.*

[54] *https://www.ahcancal.org/News-and-Communications/Fact-Sheets/FactSheets/Workforce-Survey-September2021.pdf.*

[55] See HHS OIG reports OEI–09–21–00140 and OEI–06–20–00300, both accessed September 26, 2021.

[56] *https://covid.cdc.gov/covid-data-tracker/#health-care-personnel;* accessed September 24, 2021.

[57] Analysis of dialysis facility and nursing home data reported through NHSN.

[58] Ibid. 8footnote 56.

[59] *https://emergency.cdc.gov/han/2021/han00447.asp.*

[60] Internal estimates based on data published at: *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html;* accessed September 24, 2021.

[61] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm?s_cid=mm7037e1_w.*

[62] LTC facility rates derived from data reported through CDC's NHSN and posted online at the Nursing Home COVID–19 Vaccination Data Dashboard: *https://www.cdc.gov/nhsn/covid19/ltc-vaccination-dashboard.html;* accessed September 15, 2021.

[63] Dialysis facility rates derived from data reported through CDC's NHSN and posted online at the Dialysis COVID–19 Vaccination Data Dashboard: *https://www.cdc.gov/nhsn/covid19/dial-vaccination-dashboard.html;* accessed September 15, 2021.

[64] Hospital data come from unpublished analyses of data reported to HHS and posted on HHS Protect.

[65] Ibid. footnotes 62–64.

[66] *https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html.*

[67] *https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive.html..*

[68] *https://covid.cdc.gov/covid-data-tracker/#health-care-personnel.*

reinfections.[69] Consequently, CDC recommends that all people be vaccinated, regardless of their history of symptomatic or asymptomatic SARS–CoV–2 infection.[70]

Further, the risks of unvaccinated health care staff may disproportionately impact communities who experience social risk factors and populations described under Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, including members of racial and ethnic communities; individuals with disabilities; individuals with limited English proficiency; Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ+) individuals; individuals living in rural areas; and others adversely affected by persistent poverty or inequality. CDC data show that across the U.S., physicians and advanced practice providers have significantly higher vaccination rates than aides.[71] [72] Among aides, lower vaccination coverage was observed in those facilities located in zip codes where communities experience greater social risk factors. The finding that vaccination coverage among aides was lower among those working at LTC facilities located in zip code areas with higher social vulnerability is consistent with an earlier analysis of overall county-level vaccination coverage by indices of social vulnerability.[73] CDC notes that together, these data suggest that vaccination disparities among job categories are likely to mirror social disparities as well as disparities in surrounding communities. In addition, nurses and aides who may have the most patient contact have the lowest rates of vaccination coverage among health care staff. COVID–19 outbreaks have occurred in LTC facilities in which residents were highly vaccinated, but transmission occurred through unvaccinated staff members.[74] These findings have implications regarding occupational safety and health outcome equity—national data indicates that aides in nursing homes are disproportionately women and members of racial and ethnic communities with lower hourly wages than physicians and advance practice clinicians,[75] and are also more likely to have underlying conditions that put them at risk for adverse outcomes from COVID–19.[76] Ensuring full vaccination coverage across health care settings is critical to addressing these disparities among health care workers, particularly those from communities who experience social risk, and to equitably protecting individuals CMS serves from unnecessary and significant harm associated with COVID–19 cases and the ongoing pandemic.

It is essential to reduce the transmission and spread of COVID–19, and vaccination is central to any multi-pronged approach for reducing health system burden, safeguarding health care workers and the people they serve, and ending the COVID–19 pandemic. Currently FDA-approved and FDA-authorized vaccines in use in the U.S. are both safe and highly effective at protecting vaccinated people against symptomatic and severe COVID–19.[77] Higher rates of vaccination, especially in health care settings, will contribute to a reduction in the transmission of SARS–CoV–2 and associated morbidity and mortality across providers and communities, contributing to maintaining and increasing the amount of healthy and productive health care staff, and reducing risks to patients, resident, clients, and PACE program participants.

In light of our responsibility to protect the health and safety of individuals providing and receiving care and services from for Medicare- and Medicaid-certified providers and suppliers, and CMS's broad statutory authority to establish health and safety regulations, we are compelled to require staff vaccinations for COVID–19 in these settings. For these reasons, we are issuing this IFC based on these authorities and in accordance with established rule making processes. Specifically, sections 1102 and 1871 of the Social Security Act (the Act) grant the Secretary of Health and Human Services authority to make and publish such rules and regulations, not inconsistent with the Act, as may be necessary to the efficient administration of the functions with which the Secretary is charged under this Act and as may be necessary to carry out the administration of the insurance programs under the Act. The discussions of the provider- and supplier-specific provisions in section II. of this IFC set out the specific authorities for each provider or supplier type. Provider and supplier compliance with the Federal rules issued under these statutory authorities are mandatory for participation in the Medicare and Medicaid programs.

To the extent a court may enjoin any part of the rule, the Department intends that other provisions or parts of provisions should remain in effect. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

A. Regulatory Responses to the PHE

1. Waivers

CMS and other Federal agencies have taken many actions and exercised extensive regulatory flexibilities to help health care providers contain the spread of SARS–CoV–2. When the President declares a national emergency under the National Emergencies Act or an emergency or disaster under the Stafford Act, CMS is empowered to take proactive steps by waiving certain CMS regulations, as authorized under section 1135 of the Act (''1135 waivers''). CMS may also grant certain flexibilities to skilled nursing facilities (SNFs) under Medicare, as authorized separately under section 1812(f) of the Act (''1812(f) flexibilities''). The 1135 waivers and 1812(f) flexibilities allowed us to rapidly expand efforts to help control the spread of SARS–CoV–2. We have issued PHE waivers for most Medicare- and Medicaid-certified

[69] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm?s_cid=mm7032e1_w.*

[70] *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination.*

[71] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7030a2.htm.*

[72] *https://doi.org/10.7326/M21-3150.*

[73] Hughes MM, Wang A, Grossman MK, et al. County-level COVID–19 vaccination coverage and social vulnerability—United States, December 14, 2020–March 1, 2021. MMWR Morb Mortal Wkly Rep 2021;70:431–6. *https://doi.org/10.15585/mmwr.mm7012e1external icon PMID:33764963external icon.*

[74] Cavanaugh AM, Fortier S, Lewis P, et al. COVID–19 outbreak associated with a SARS–CoV–2 R.1 lineage variant in a skilled nursing facility after vaccination program—Kentucky, March 2021. MMWR Morb Mortal Wkly Rep 2021;70:639–43. *https://doi.org/10.15585/mmwr.mm7017e2external≤ icon PMID:33914720external icon.*

[75] Bureau of Labor Statistics. May 2020 national occupational employment and wage estimates. Washington, DC: US Department of Labor, Bureau of Labor Statistics; 2021. Accessed May 1, 2021. *https://www.bls.gov/oes/current/oes_nat.htm#00-0000externalicon.*

[76] Silver SR, Li J, Boal WL, Shockey TL, Groenewold MR. Prevalence of underlying medical conditions among selected essential critical infrastructure workers—behavioral risk factor surveillance system, 31 states, 2017–2018. MMWR Morb Mortal Wkly Rep 2020;69:1244–9. *https://doi.org/10.15585/mmwr.mm6936a3external icon PMID:32914769external icon.*

[77] *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html.* Accessed 10/14/2021.

providers and suppliers, with the goal of supporting each facility's operational flexibility while preserving health and safety and core health care functions.

2. Rulemaking

Since the onset of the PHE, we have issued five IFCs to help contain the spread of SARS–CoV–2. On April 6, 2020, we issued an IFC (Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency (85 FR 19230 through 19292), which established that certain requirements for face-to-face/in-person encounters will not apply during the PHE for COVID–19 effective for claims with dates of service on or after March 1, 2020, and for the duration of the PHE for COVID–19. On May 8, 2020, we issued a second IFC (Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program (85 FR 27550 through 27629)) (''May 8, 2020 COVID–19 IFC''). This second IFC contained additional information on changes Medicare made to existing regulations to provide flexibilities for Medicare beneficiaries and providers to respond effectively to the PHE for COVID–19. On September 2, 2020, we issued a third IFC (Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency (85 FR 54820 through 54874)) (''September 2, 2020 COVID–19 IFC''), that included new requirements for hospitals and CAHs to report data in accordance with a frequency and in a standardized format as specified by the Secretary during the PHE for COVID–19. On November 6, 2020, we issued a fourth IFC (Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency (85 FR 71142 through 71205)). This IFC discussed CMS's implementation of section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which established Medicare Part B coverage and payment for Coronavirus Disease 2019 (COVID–19) vaccine and its administration. This IFC implemented requirements in the CARES Act that providers of COVID–19 diagnostic tests make public their cash prices for those tests and established an enforcement scheme to enforce those requirements. This IFC also established an add-on payment for cases involving the use of new COVID–19 treatments under the Medicare Inpatient Prospective Payment System (IPPS). Most recently, on May 13, 2021, we issued the fifth IFC (Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff (86 FR 26306)) (''May 13, 2021 COVID–19 IFC''), that revised the infection control requirements that LTC facilities and ICFs-IID must meet to participate in the Medicare and Medicaid programs.

OSHA has also engaged in rulemaking in response to the PHE for COVID–19. On June 21, 2021, OSHA issued the COVID–19 Healthcare Emergency Temporary Standard (ETS) at 29 CFR 1910 subpart U (86 FR 32376) to protect health care and health care support service workers from occupational exposure to COVID–19.[78] Health care employers covered by the ETS must develop and implement a COVID–19 plan for each workplace to identify and control COVID–19 hazards in the workplace and implement requirements to reduce transmission of SARS–CoV–2 in their workplaces related to the following: (1) Patient screening and management, (2) standard and transmission-based precautions, (3) personal protective equipment (including facemasks, and respirators), (4) controls for aerosol-generating procedures performed on persons with suspected or confirmed COVID–19, (5) physical distancing, (6) physical barriers, (7) cleaning and disinfection, (8) ventilation, (9) health screening and medical management, (10) training, (11) anti-retaliation, (12) recordkeeping, and, (13) reporting. In addition, the ETS requires covered employers to support COVID–19 vaccination for each employee by providing reasonable time and paid leave for employees to receive vaccines and recover from side effects.

The ETS generally applies to all workplace settings where any employee provides health care services or health care support services; however, because the ETS targets settings where care is provided for individuals with known or suspected COVID–19, the rule contains several exceptions. The ETS does not apply to: (1) Provision of first aid by any employee who is not a licensed health care provider, (2) dispensing of prescriptions by pharmacists in retail settings, (3) non-hospital ambulatory care settings where all non-employees are screened prior to entry, and people with suspected or confirmed COVID–19 are not permitted to enter, (4) well-defined hospital ambulatory care settings where all employees are fully vaccinated, all non-employees are screened prior to entry, and people with suspected or confirmed COVID–19 are not permitted to enter, (5) home health care settings where all employees are fully vaccinated, all non-employees are screened prior to entry, and people with suspected or confirmed COVID–19 are not present, (6) health care support services not performed in a health care setting (for example, offsite laundry, off-site medical billing), and (7) telehealth services performed outside of a setting where direct patient care occurs. Furthermore, in well-defined areas where there is no reasonable expectation that any person with suspected or confirmed COVID–19 will be present, the ETS exempts fully vaccinated workers from masking, distancing, and barrier requirements.

Moreover, the ETS requires employers to immediately remove employees from the workplace if they (1) have tested positive for COVID–19, (2) have been diagnosed with COVID–19 by a licensed health care provider, (3) have been advised by a licensed health care provider that they are suspected to have COVID–19, or (4) are experiencing certain symptoms (defined as either loss of taste and/or smell with no other explanation, or fever of at least 100.4 degrees Fahrenheit and new unexplained cough associated with shortness of breath). Employers must also immediately remove an employee who was not wearing a respirator and any other required PPE and had been in close contact with a COVID–19 positive person in the workplace. However, removal from the workplace due to instances of close contact exposure in the workplace is not required for asymptomatic employees who either had COVID–19 and recovered with the last 3 months, or have been fully vaccinated (that is, 2 or more weeks have passed since the final dose).

Complementary to the OSHA ETS, this interim final rule requires certain providers and suppliers participating in Medicare and Medicaid programs to ensure staff are fully vaccinated for COVID–19, unless exempt, because vaccination of staff is necessary for the health and safety of individuals to whom care and services are furnished. Health care staff are at high risk for SARS–CoV–2 exposure, the virus that causes COVID–19, due to interactions with patients and individuals in the

[78] *https://www.osha.gov/coronavirus/ets.* Accessed 10/6/2021.

community.[79] Receiving a complete primary vaccination series reduces the risk of COVID–19 by 90 percent or more thereby inhibiting the spread of disease to others.[80] Furthermore, a COVID–19 vaccination requirement reduces the likelihood of medical removal of health care staff from the workplace, as required by the OSHA COVID–19 Healthcare ETS. This is yet another way in which this interim final rule protects the individuals who receive services from the providers and suppliers to whom the rule applies by minimizing unpredictable disruptions to operations and care.

OSHA is the Federal agency responsible for setting and enforcing standards to ensure safe and healthy working conditions for workers. The COVID–19 Healthcare ETS addresses protections for health care and health care support service workers from the grave danger of COVID–19 exposure in certain workplaces. CMS is the Federal agency responsible for establishing health and safety regulations for Medicare- and Medicaid-certified providers and suppliers. Hence, we are establishing a final rule requiring COVID–19 vaccination of staff to safeguard the health and safety of patients, residents, clients, and PACE program participants who receive care and services from those providers and suppliers. Providers and suppliers may be covered by both the OSHA ETS and our interim final rule. Although the requirements and purpose of each regulation text are different, they are complementary.

B. COVID–19 Vaccine Development and Approval

FDA analysis has shown that all of the currently approved or authorized vaccines are safe and CDC reports that over 408 million doses of the vaccine have been given through October 18, 2021.[81] Bringing a new vaccine to the public involves many steps, including vaccine development, clinical trials, and U.S. Food and Drug Administration (FDA) authorization or approval. While COVID–19 vaccines were developed rapidly, all steps have been taken to ensure their safety and effectiveness. Scientists have been working for many years to develop vaccines against coronaviruses, such as those that cause severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). SARS–CoV–2, the virus that causes COVID–19, is related to these other coronaviruses and the knowledge that was gained through past research on coronavirus vaccines helped speed up the initial development of the current COVID–19 vaccines. After initial development, vaccines go through three phases of clinical trials to make sure they are safe and effective. For other vaccines routinely used in the U.S., the three phases of clinical trials are performed one at a time. During the development of COVID–19 vaccines, these phases overlapped to speed up the process so the vaccines could be used as quickly as possible to control the pandemic. No trial phases were skipped.[82]

All COVID–19 vaccines currently licensed (approved) [83] or authorized for use in the U.S. were tested in clinical trials involving tens of thousands of people. FDA evaluated all of the information submitted to it in requests for Emergency Use Authorization (EUA) for the authorized COVID–19 vaccines and, for the Comirnaty COVID–19 Vaccine, in a Biologics License Application (the conventional path to FDA approval of a vaccine). FDA determined that these vaccines meet FDA's standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization and licensure, as applicable. The clinical trials included participants of different races, ethnicities, and ages, including adults over the age of 65.[84] Because COVID–19 continues to be widespread, researchers have been able to conduct vaccine clinical trials more quickly than if the disease were less common. Side effects following vaccination are dependent on the specific vaccine that an individual receives, and the most common include pain, redness, and swelling at the injection site, tiredness, headache, muscle pain, nausea, vomiting, fever, and chills.[85] After a review of all available information, the Advisory Committee on Immunization Practices (ACIP) and CDC have concluded the lifesaving benefits of COVID–19 vaccination outweigh the risks or possible side effects.[86]

The COVID–19 vaccines currently licensed or authorized for use in the U.S. are generally administered as either a single dose or a two-dose series given at least 21 or 28 days apart. Following completion of that primary series, a subsequent dose or doses may be recommended for one of two purposes. In the first instance, an additional dose of vaccine is administered when the immune response following a primary vaccine series is likely to be insufficient. In other words, the additional dose augments the original primary series. Currently, the EUA for the Moderna mRNA COVID–19 vaccine has been amended to include the use of a third primary series dose (that is, ''additional dose'') in certain immunocompromised individuals 18 years of age or older. Similarly, the EUA for the Pfizer BioNTech mRNA COVID–19 vaccine has been amended to include the use of an additional, or third primary series, dose in certain immunocompromised individuals 12 years of age and older.

In the second instance, a booster dose of vaccine is administered when the initial immune response to a primary vaccine series is likely to have waned over time. In other words, although an adequate immune response occurred after the primary vaccine series, over time, immunity decreases.[87] [88] [89] On September 22, 2021, the FDA amended the EUA for the Pfizer BioNTech mRNA COVID–19 vaccine to allow for use of a single booster dose in certain individuals, to be administered at least 6 months after completion of the primary series. Specifically, this booster dose is authorized for individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID–19, and individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS–CoV–2 puts them at high risk of serious complications of COVID–19 including severe COVID–19.[90]

[79] *https://www.cdc.gov/mmwr/volumes/69/wr/mm6938a3.htm?s_cid=mm6938a3_w.* Accessed10/16/2021.

[80] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/work.html.* Accessed 10/16/2021.

[81] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=Millions%20of%20people%20in%20the,monitoring%20in%20US%20history.*

[82] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/distributing/steps-ensure-safety.html.*

[83] ''Licensed'' is the statutory term under section 351 of the Public Health Service Act for what is commonly referred to as approval of a biological product. For purposes of this rulemaking, the terms 'approved' or 'licensed' and 'approval' or 'licensure' are being used interchangeably with respect to COVID–19 vaccines.

[84] *https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-diversity-within-covid-19-vaccine-clinical-trials-key-questions-and-answers/.*

[85] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html.*

[86] See Centers for Disease Control and Prevention. Benefits of Getting a COVID–19 Vaccine. *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html.* Updated January 5, 2021. Accessed January 14, 2021.

[87] Summaries of evidence presented to CDC's Advisory Council on Immunization Practices available at *https://www.cdc.gov/vaccines/acip/meetings/slides-2021-09-22-23.html.*

[88] *https://www.nejm.org/doi/full/10.1056/NEJMoa2114583.*

[89] *https://www.medrxiv.org/content/10.1101/2020.10.26.20219725v1.*

[90] *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine.*

Throughout this rule, we will use the terms ''additional dose'' and ''booster'' to differentiate between the two use cases outlined above.

Every person who receives a COVID–19 vaccine receives a vaccination record card noting which vaccine and the dose that was received. Vaccine materials specific to each vaccine are located on CDC [91] and FDA [92] websites. CDC has posted a collection of informational toolkits for specific communities and settings at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/toolkits.html.* These toolkits provide staff, facility administrators, clinical leadership, caregivers, and health care consumers with information and resources.

While we are not requiring participation, we encourage staff who use smartphones to use CDC's smartphone-based tool called ''v-safe After Vaccination Health Checker'' (v-safe) [93] to self-report on one's health after receiving a COVID–19 vaccine. V-safe is a program that differs from the Vaccine Adverse Event Reporting System (VAERS), which we discuss in section I.C. of this rule. Individuals may report adverse reactions to a COVID–19 vaccine to either program. Enrollment in v-safe allows any participating vaccine recipient to directly and efficiently report to CDC how they are feeling after receiving a specific vaccine, including any problems or adverse reactions. When an individual receives the vaccine, they should also receive a v-safe information sheet telling them how to enroll in v-safe or they can register at *http://www.vsafe.cdc.gov.* Individuals who enroll will receive regular text messages providing links to surveys where they can report any problems or adverse reactions after receiving a COVID–19 vaccine, as well as receive ''check-ins,'' and reminders for a second dose if applicable.[94] We note again that participation in v-safe is not mandatory, and further that staff participation and any health information provided is not traced to or shared with employers.

Based on current CDC guidance,[95] individuals are considered fully vaccinated for COVID–19 14 days after receipt of either a single-dose vaccine (Janssen/Johnson & Johnson) or the second dose of a two-dose primary vaccination series (Pfizer-BioNTech/Comirnaty or Moderna). This guidance can also be applied to COVID–19 vaccines listed for emergency use by the World Health Organization (WHO) and some vaccines used in COVID–19 clinical trials conducted in the U.S. These circumstances are addressed in more detail in section I.C. of this IFC. To improve immune response for those individuals with moderately to severely compromised immune systems who receive the Pfizer-BioNTech Vaccine, Comirnaty, or Moderna Vaccine, the CDC advises an additional (third) dose of an mRNA COVID–19 vaccine after completing the primary vaccination series.[96] In addition, certain individuals who received the Pfizer-BioNTech COVID–19 Vaccine may receive a booster dose at least 6 months after completing the primary vaccination series.[97]

This IFC requires Medicare- and Medicaid-certified providers and suppliers to ensure that staff are fully vaccinated for COVID–19, unless the individual is exempted. Consistent with CDC guidance, we consider staff fully vaccinated if it has been 2 or more weeks since they completed a primary vaccination series for COVID–19. We define completion of a primary vaccination series as having received a single-dose vaccine or all doses of a multi-dose vaccine. Currently, CDC guidance does not include either the additional (third) dose of an mRNA COVID–19 vaccine for individuals with moderately or severely immunosuppression or the booster dose for certain individuals who received the Pfizer-BioNTech Vaccine in their definition of fully vaccinated.[98] Therefore, for purposes of this IFC, neither additional (third) doses nor booster doses are required. The OSHA Emergency Temporary Standard for Healthcare discussed in section I.A.2. of this IFC also defines fully vaccinated in accordance with CDC guidance. Hence, definitions of fully vaccinated are consistent among the requirements in these regulations.

C. Administration of Vaccines Outside the U.S., Listed for Emergency Use by the WHO, Heterologous Primary Series, and Clinical Trials

We expect the majority of staff will likely receive a COVID–19 vaccine authorized for emergency use by the FDA or licensed by the FDA. Currently, this would include the authorized Pfizer-BioNTech (interchangeable with the licensed Comirnaty vaccine made by Pfizer for BioNTech), Moderna, and Janssen (Johnson & Johnson) COVID–19 vaccines. We also expect COVID–19 vaccine administration will likely occur within the U.S. for the majority of staff. However, some staff may receive FDA approved or authorized COVID–19 vaccines outside of the U.S., vaccines administered outside of the U.S. that are listed by the WHO for emergency use that are not approved or authorized by the FDA, or vaccines during their participation in a clinical trial at a site in the U.S. For these staff, we defer to CDC guidance for COVID–19 vaccination briefly discussed here. For more information, providers and suppliers should consult the CDC website at *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#.*

Repeat vaccine doses are not recommended by CDC for individuals who previously completed the primary series of a vaccine approved or authorized by the FDA, even if administration of the vaccine occurred outside of the U.S. Individuals who receive a COVID–19 vaccine for which two doses are required to complete the primary vaccination series should adhere as closely as possible to the recommended intervals. Following completion of their second dose, certain individuals who had received the Pfizer-BioNTech COVID–19 vaccine may receive a booster dose at least 6 months after completion of the primary vaccination series. Moderately to severely immunocompromised individuals who have received 2 doses of an mRNA vaccine may receive a third dose at least 28 days after the second dose. Vaccine administration may occur inside or outside of the U.S.

Furthermore, the WHO maintains a list of COVID–19 vaccines for emergency use.[99] The CDC advises that doses of an FDA approved or authorized COVID–19 vaccine are not recommended for individuals who have previously completed the primary series of a vaccine listed for emergency use by

[91] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html.*

[92] *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.*

[93] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.*

[94] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html.*

[95] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html.* Accessed 10/16/2021.

[96] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html.* Accessed 10/14/2021.

[97] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html.* Accessed 10/16/2021.

[98] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html.* Accessed 10/16/2021.

[99] *https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines.* Accessed September 14, 2021.

the WHO. For those who have not completed the primary series of a vaccine listed for emergency use by the WHO, they may receive an FDA approved or authorized COVID–19 vaccination series. In addition, individuals who have received a COVID–19 vaccine that is neither approved nor authorized by the FDA, nor listed on the WHO emergency use list, may receive an FDA approved or authorized vaccination series. The CDC guidelines recommend at least 28 days between administration of an FDA licensed or authorized vaccine, a non-FDA approved or authorized vaccine, and a vaccine listed by WHO for emergency use.

For the completion of the primary series of COVID–19 vaccination, individuals should generally avoid using heterologous vaccines—meaning receiving doses of different vaccines—to complete a primary COVID–19 vaccination series. Nevertheless, CDC does recognize that, in certain situations (for example, when the vaccine product given for the first dose cannot be determined or is no longer available), a different vaccine may be used to complete the primary COVID–19 vaccination series. Accordingly, staff may be considered compliant with the requirements within this regulation if they have received any combination of two doses of a vaccine licensed or authorized by the FDA or listed on the WHO emergency use list as part of a two-dose series. Of note, the recommended interval between the first and second doses of a vaccine licensed or authorized by FDA, or listed on the WHO emergency use list, varies by vaccine type. For *interpretation of vaccination records and compliance* with this rule, people who received a heterologous primary series (with any combination of FDA-authorized, FDA-approved, or WHO EUL-listed products) can be considered fully vaccinated if the second dose in a two dose heterologous series must have been received no earlier than 17 days (21 days with a 4 day grace period) after the first dose.[100] Because the science and clinical recommendations are evolving rapidly, we refer individuals to CDC's *Interim Public Health Recommendations for Fully Vaccinated People* for additional details.

Some staff may receive COVID–19 vaccines due to their participation in a clinical trial at a site in the U.S. Repeat vaccine doses are not recommended by CDC for participants in a clinical trial who previously completed the primary series of a vaccine approved or authorized by FDA, or listed for emergency use by the WHO. Likewise, for individuals who participated in a clinical trial at a site in the U.S. and received the full series of an ''active'' vaccine candidate (not placebo) and ''vaccine efficacy has been independently confirmed (for example, by a data and safety monitoring board),'' CDC does not recommend repeat doses.[101]

D. FDA Emergency Use Authorization (EUA) and Licensure of COVID–19 Vaccines

The FDA provides scientific and regulatory advice to vaccine developers and undertakes a rigorous evaluation of the scientific information it receives from all phases of clinical trials; such evaluation continues after a vaccine has been licensed by FDA or authorized for emergency use. On August 23, 2021, FDA licensed the first COVID–19 vaccine. The vaccine had been known as the Pfizer-BioNTech COVID–19 vaccine, and will now be marketed as Comirnaty, for the prevention of COVID–19 in individuals 16 years of age and older.[102] The vaccine continues to be available in the U.S. under EUA, including for individuals 12 through 15 years of age. This EUA has been amended to allow for the use of a third dose for certain immunocompromised individuals 12 years of age and older. This EUA has also been amended to allow for use of a single booster dose in certain individuals. FDA has issued EUAs for two additional vaccines for the prevention of COVID–19, one for the Moderna COVID–19 vaccine (December 18, 2020) (indicated for use in individuals 18 years of age and older), and the other for Janssen (Johnson & Johnson) COVID–19 Vaccine (February 27, 2021) (indicated for use in individuals 18 years of age and older). The EUA for the Moderna COVID–19 vaccine has been amended to allow for the use of a third dose in certain immunocompromised individuals. Package inserts and fact sheets for health care providers administering COVID–19 vaccines are available for each licensed and authorized vaccine from the FDA.[103] [104] [105]

Section 564 of the Federal Food, Drug, and Cosmetic Act authorizes FDA to issue EUAs. An EUA is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID–19 pandemic. FDA may authorize certain unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents when certain criteria are met, including there are no adequate, approved, and available alternatives.[106]

The safety of the approved and authorized COVID–19 vaccines is closely monitored. VAERS is a safety and monitoring system that can be used by anyone to report adverse events after vaccines. For COVID–19 vaccines, vaccination providers and licensed and authorized vaccine manufacturers, must report select adverse events to VAERS following receipt of COVID–19 vaccines (including serious adverse events, cases of multisystem inflammatory syndrome (MIS), and COVID–19 cases that result in hospitalization or death).[107] Providers also must adhere to any revised safety reporting requirements. FDA's website includes letters of authorization and fact sheets and these documents should be checked for any updates that may occur. Other adverse events following vaccination may also be reported to VAERS. Additionally, adverse events are also monitored through electronic health record- and claims-based systems (through CDC's Vaccine Safety Datalink and FDA's Biologics Effectiveness and Safety System (BEST)).

FDA is closely monitoring the safety of the COVID–19 vaccines both authorized for emergency use and licensed use. Vaccination providers are responsible for mandatory reporting to VAERS of certain adverse events as listed on the Health Care Provider Fact Sheets for the authorized COVID–19 vaccines and for Comirnaty.

Vaccine safety is critically important for all vaccination programs. Side effects following vaccinations often include swelling, redness, and pain at the injection site; flu-like symptoms; headache; and nausea; all typically of

[100] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html.*

[101] *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#* Accessed 9/14/2021.

[102] *https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine* Accessed 10/14/2021.

[103] Pfizer Fact Sheet—*https://www.fda.gov/media/144413/download.*

[104] Moderna Fact Sheet—*https://www.fda.gov/media/144637/download.*

[105] Janssen Fact Sheet—*https://www.fda.gov/media/146304/download.*

[106] *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

[107] Department of Health and Human Services. VAERS—Vaccine Adverse Event Reporting System. Accessed at *https://vaers.hhs.gov/.* Accessed on January 26, 2021.

short duration.[108] Serious adverse reactions also have been reported following COVID–19 vaccines; however, they are rare.[109] [110] For example, it is estimated that anaphylaxis following the mRNA COVID–19 vaccines occurs in 2–5 individuals per million vaccinated (*https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html*). For these individuals, another shot of an mRNA COVID–19 vaccine is not recommended,[111] and they should discuss receiving a different type of COVID–19 vaccine with their health care practitioner.[112] Other rare serious adverse reactions that have been reported to occur following COVID–19 vaccines include thrombosis with thrombocytopenia syndrome (TTS) following the Janssen COVID–19 vaccine and myocarditis and/or pericarditis following the mRNA COVID–19 vaccines (*https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html*). In the face of the COVID–19 pandemic, global researchers were able to build upon decades of vaccine development, research, and use to produce safe vaccines that have been highly effective in protecting individuals from COVID–19. From December 14, 2020, through October 12, 2021, over 403 million doses of COVID–19 vaccine have been administered in the U.S. *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html.* ''CDC recommends everyone 12 years and older get vaccinated as soon as possible to help protect against COVID–19 and the related, potentially severe complications that can occur.'' [113] They state that the ''potential benefits of COVID–19 vaccination outweigh the known and potential risks, including the possible risk of myocarditis or pericarditis.'' [114]

[108] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html.* Accessed 10/17/2021.

[109] Ibid.

[110] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.* Access 10/17/2021.

[111] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html.* Accessed 10/17/2021.

[112] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/specific-groups/allergies.html#anchor_1624541541034.* Accessed 10/17/2021.

[113] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.* Accessed 10/17/2021.

[114] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html.* Accessed 10/17/2021.

E. COVID–19 Vaccine Effectiveness

COVID–19 vaccines currently approved or authorized by FDA are highly effective in preventing serious outcomes of COVID–19, including severe disease, hospitalization, and death.[115] Moreover, available evidence suggests that these vaccines offer protection against known variants, including the Delta variant (B.1.617.2), particularly against hospitalization and death.[116] [117] Furthermore, a recent study found that, between December 14, 2020, and August 14, 2021, full vaccination with COVID–19 vaccines was 80 percent effective in preventing RT–PCR–confirmed SARS-CoV–2 infection among frontline workers, further affirming the highly protective benefit of full vaccination up to and through the 2021 summer COVID–19 pandemic waves in the U.S.[118] While vaccine effectiveness point estimates did decline over the course of the study as the Delta variant became predominant, the protection afforded by vaccination remained significant, underscoring the continued importance and benefits of COVID–19 vaccination.[119]

Like most vaccines, COVID–19 vaccines are not 100 percent effective in preventing COVID–19. Consequently, some ''breakthrough'' cases are expected and, as the number of people who have completed a primary vaccination series and are considered fully vaccinated for COVID–19 increases, breakthrough COVID–19 cases will also increase commensurately. However, the risk of developing COVID–19, including severe illness, remains much higher for unvaccinated than vaccinated people. Vaccinated people with a breakthrough COVID–19 case are less likely to develop serious disease, be hospitalized, and die than those who are unvaccinated and get COVID–19.[120] The combined protections offered by vaccination and ongoing implementation of other infection control measures, especially source control (masking),[121] remain critical to safeguarding patients, residents, clients, PACE program participants, and staff.

[115] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/work.html.*

[116] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e2.htm?s_cid=mm7034e2_w.*

[117] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e1.htm?s_cid=mm7034e1_w.*

[118] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm#contribAff.*

[119] *https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html?s_cid=11504:cdc%20delta%20variant%20vaccine%20effectiveness:sem.ga:p:RG:GM:gen:PTN:FY21.*

[120] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/why-measure-effectiveness/breakthrough-cases.html.*

[121] *https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.* Accessed 10/15/2021.

F. Stakeholder Response to Vaccines

There has been growing national interest in COVID–19 vaccination requirements among health care workers, including requests from various national health care stakeholders. In a joint statement released on July 26, 2021, more than 50 health care professional societies and organizations called for all health care employers and facilities to require that all their staff be vaccinated against COVID–19. Included as signatories to this statement were organizations representing millions of workers throughout the U.S. health care industry, including those representing doctors, nurses, pharmacists, physician assistants, public health workers, and epidemiologists as well as long term care, home care, and hospice workers.[122]

In addition, a large nonprofit, nonpartisan organization focused on empowering Americans over the age of 50 recently called on all LTC facilities to require vaccinations for staff and residents.[123] A non-profit organization dedicated to advancing dignity in aging issued a statement in support of COVID–19 vaccine mandates for staff and residents of long-term care facilities.[124] In a policy statement dated July 21, 2021, a large long term care association, ''strongly urges all residents and staff in long-term care to get vaccinated'' and ''supports requiring vaccines for current and new staff in long-term care and other healthcare settings. COVID–19 vaccination should be a condition of employment for all healthcare workers, including employees, contract staff and others, with appropriate exemptions for those with medical reasons or as specified by federal or state law.'' [125] The statement further notes that ''COVID–19 vaccines are safe . . . effective for preventing infection, and especially severe illness and death [and] reduce the risk of spreading the virus.'' [126] Moreover, the

[122] *https://www.hematology.org/newsroom/press-releases/2021/joint-statement-in-support-of-covid-19-vaccine-mandates-for-all-workers-in-health.*

[123] *https://press.aarp.org/2021-8-12-New-AARP-Analysis-Shows-Nursing-Homes-Vaccination-Rates-Still-Well-Short-of-Benchmark-as-COVID-Cases-Trend-Upwards.*

[124] *https://justiceinaging.org/justice-in-aging-supports-mandatory-covid-vaccinations-in-long-term-care-facilities/,* accessed 10/6/21, 1:02 p.m. EDT.

[125] *https://leadingage.org/sites/default/files/LeadingAge%20Statement%20on%20Vaccine%20Mandates%20for%20Healthcare%20Workers.pdf.*

[126] Ibid.

statement observes that ''the COVID crisis exacerbated long-standing workforce challenges, and some in the sector fear that a vaccine mandate could lead to worker resignations. But providers that have required staff vaccination have reported high vaccine accepted by previously hesitant care professionals, and many providers report that when staff vaccination rates are high, they become providers of choice in their communities.'' [127] A non-profit federation of affiliated State health organizations, representing more than 14,000 non-profit and for-profit nursing homes, assisted living communities, and facilities for individuals with disabilities expressed support for all health care ''strongly urges the vaccination of all health care personnel'' to ''protect all residents, staff and others in our communities from the known and substantial risks of COVID–19.'' They also assert that ''COVID–19 vaccines protect health care personnel when working both in health care facilities and in the community,'' and ''provide strong protection against workers unintentionally carrying the disease to work and spreading it to patients and peers.'' [128]

Numerous health systems and individual health care employers across the country have implemented vaccine mandates independent of this rule. For example, a health care system that is the largest private employer in Delaware with more than 14,000 employees, a health care system and academic medical center with over 26,000 employees in Texas, and an integrated health system in North Carolina with more than 35,000 employees, to name a few, have all preceded this rule with their own vaccination requirements, achieving rates of at least 97 percent vaccination among their staff.[129] [130] [131] [132] These organizations are already realizing the effectiveness of strong vaccination policies. Despite the successes of these organizations in increasing levels of staff vaccination, there remains an inconsistent patchwork of requirements and laws that is only effective at local levels and has not successfully raised staff vaccination rates nationwide. Patients, residents, clients, PACE program participants, and staff alike are not adequately protected from COVID–19.

In September 2021, Jeffrey Zients, the White House Coronavirus Response Coordinator, noted that ''vaccination requirements work . . . and are the best path out of the pandemic.'' He further noted that vaccination requirements are not only key to the nation's path out of the pandemic, but also accelerate our economic recovery, keeping workplaces safer, and helping to curb the spread of the virus in communities, and boost job growth, the labor market, and the nation's overall economy.

G. Populations at Higher Risk for Severe COVID–19 Outcomes

COVID–19 can affect anyone, with symptoms ranging from mild (infections not requiring hospitalization) to very severe (requiring intensive care in a hospital). Nonetheless, studies have shown that COVID–19 does not affect all population groups equally.[133] Age remains a strong risk factor for severe COVID–19 outcomes. Approximately 54.1 million people aged 65 years or older reside in the U.S.; this age group accounts for more than 80 percent of U.S. COVID–19 related deaths. Residents of LTC facilities make up less than 1 percent of the U.S. population but accounted for more than 35 percent of all COVID–19 deaths in the first 12 months of the pandemic.[134]

Additionally, adults of any age with certain underlying medical conditions are at increased risk for severe illness from COVID–19. These include, but are not limited to, cancer, cerebrovascular disease, diabetes (Type 1 and Type 2), chronic kidney disease, COPD, heart conditions, Down Syndrome, obesity, substance use, smoking status, and pregnancy.[135] The risk of severe COVID–19 also increases as the number of underlying medical conditions increases in a particular individual.

A confluence of structural and epidemiological factors has also contributed to disparate risk for COVID–19 infection, severe illness, and death in certain populations. For example, evidence clearly indicates that racial and ethnic minority groups, including Black and Hispanic or Latino, have disproportionately higher hospitalization rates among every age group, including children aged younger than 18 years.[136] These same groups are disproportionately affected by long-standing inequities in social determinants of health, such as poverty and health care access, that increase risk of severe illness and death from COVID–19.[137] People with intellectual disabilities are more likely to have chronic health conditions, live in congregate settings, and face more barriers to health care; some studies suggest they are also more likely to get COVID–19 and have worse outcomes.[138] Finally, rural communities often have a higher proportion of residents who live with comorbidities or disabilities and are aged ≥65 years; these risk factors, combined with more limited access to health care facilities with intensive care capabilities, place rural dwellers at increased risk for COVID–19-associated morbidity and mortality.[139]

In addition, CDC data indicate that vaccination rates are disproportionately low among nurses and health care aides in long term care settings, particularly in communities that experience social risk factors. Further, CDC data indicate that nurses and aides in these settings are more likely to be members of racial and ethnic minority communities.[140] This disparity in vaccination coverage may be exacerbating existing and emerging disparities related to COVID–19 cases and impact, placing members of communities who experience social risk factors—those in rural areas with geographic and transportation barriers to care, those in low income areas who experience persistent poverty and inequality, and others—at further increased risk for COVID–19-associated morbidity and mortality.[141] This disparity may be, in part, reduced by the potential positive health equity impacts of requiring staff vaccination among provider and supplier types subject to rulemaking.

[127] Ibid.

[128] *https://www.ahcancal.org/News-and-Communications/Press-Releases/Pages/AHCANCAL-Issues-Policy-Statement-Regarding-COVID-19-Vaccinations-of-Long-Term-Care-Personnel.aspx.* Accessed 10/16/2021.

[129] *https://news.christianacare.org/2021/09/safe-care-safe-workplace-we-are-vaccinated/.* Accessed 10/15/2021.

[130] *https://www.delawareonline.com/story/news/health/2021/09/27/christianacare-fires-employees-not-complying-vaccine-mandate/5887784001/.* Accessed 10/15/2021.

[131] *https://www.houstonmethodist.org/leading-medicine-blog/articles/2021/jun/houston-methodist-requires-covid-19-vaccine-for-credentialed-doctors/.* Accessed 10/15/202021.

[132] *https://www.novanthealth.org/home/about-us/newsroom/press-releases/newsid33987/2576/novant-health-update-on-mandatory-covid-19-vaccination-program-for-employees.aspx.* Accessed 10/15/2021.

[133] *https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html.*

[134] *https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html.*

[135] *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/underlying-evidence-table.html.*

[136] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/disparities-hospitalization.html.*

[137] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/disparities-illness.html.*

[138] *https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0051.*

[139] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e3.htm.*

[140] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7030a2.htm.*

[141] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/vaccine-equity.html.*

CMS believes that the developing data about staff vaccination rates and rates of COVID–19 cases, and the urgent need to address COVID-related staffing shortages that are disrupting patient access to care, provides strong justification as to the need to issue this IFC requiring staff vaccination for most provider and supplier types over which we have authority.

H. CMS Authority To Require Staff Vaccinations

CMS has broad statutory authority to establish health and safety regulations, which includes authority to establish vaccination requirements. Section 1102 of the Act grants the Secretary of Health and Human Services authority to make and publish such rules and regulations, not inconsistent with the Act, as may be necessary to the efficient administration of the functions with which the Secretary is charged under the Act. Section 1871 of the Act grants the Secretary of Health and Human Services authority to prescribe regulations as may be necessary to carry out the administration of the Medicare program. The statutory authorities to establish health and safety requirements for COVID–19 vaccination for each provider and supplier included in this IFC are listed in Table 1 and discussed in sections II.C. through II.F. of this IFC.

TABLE 1: Authorities for All Providers and Suppliers

Provider/Supplier	Statutory Authority
Ambulatory Surgical Centers (ASCs)	Sections 1102, 1832(a)(2)(f)(i), and 1833 (i)(1)(A), and 1871 of the Act
Hospices	Sections 1102,1861(dd), and 1871 of the Act
Psychiatric Residential Treatment Facilities (PRTFs)	Section 1102 and 1905(h)(1) of the Act
Programs of All-Inclusive Care for the Elderly (PACE)	Sections 1102, 1871, 1894, and 1934 of the Act
Hospitals	Sections 1102, 1861(e)(9), and 1871 of the Act
Long Term Care (LTC) Facilities	Sections 1102, 1819, 1871, and 1919 of the Act
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID)	Sections 1102 and 1905(d)(1) of the Act
Home Health Agencies (HHAs)	Sections 1102, 1861(m), 1861(o), 1871, and 1891 of the Act
Comprehensive Outpatient Rehabilitation Facilities (CORFs)	Sections 1102, 1861(cc)(2)(J), and 1871 of the Act
Critical Access Hospitals (CAHs)	Sections 1102, 1820(e), and 1871 of the Act
Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (Organizations)	Sections 1102, 1861(p)(4), and 1871 of the Act
Community Mental Health Centers (CMHCs)	Sections 1102, 1861(ff)(3), 1832(a)(2)(J), 1866(e)(2), and 1871 of the Act
Home Infusion Therapy (HIT) Suppliers	Sections 1102, 1861(iii)(3)(D)(i)(IV), and 1871 of the Act
Rural Health Clinics (RHCs)/ Federally Qualified Health Centers (FQHCs)	Sections 1102, 1861(aa), 1871, and 1905(l)(2)(B) of the Act
End-Stage Renal Disease (ESRD) Facilities	Sections 1102, 1871, and 1881(b)(1)(A) of the Act

Section 1863 of the Act provides that ''[i]n carrying out his functions, relating to determination of conditions of participation by providers . . . the Secretary shall consult with appropriate State agencies and recognized national listing or accrediting bodies[.]'' For the reasons discussed in greater detail throughout sections I. through III. this IFC, the COVID–19 pandemic presents a serious and continuing threat to the health and to the lives of staff of health care facilities and of consumers of these providers' and suppliers' services. This threat has grown to be particularly severe since the emergence of the Delta variant. Any delay in the implementation of this rule would result in additional deaths and serious illnesses among health care staff and consumers, further exacerbating the newly-arising, and ongoing, strain on the capacity of health care facilities to serve the public. For these reasons, in carrying out the agency's functions relating to determination of conditions of participation, conditions for coverage, and requirements, we intend to engage in consultations with appropriate State agencies and listing or accrediting bodies following the issuance of this rule, and toward that end we invite these entities to submit comments on this IFC. Given the urgent need to issue this rule, however, we do not believe that there exists an entity with which it would be appropriate to engage in these consultations in advance of issuing this IFC, nor do we understand the statute to impose a temporal requirement to do so in advance of the issuance of this rule.

We have not previously required any vaccinations, but we recognize that many health care workers already comply with employer or State government vaccination requirements (for example, influenza, and hepatitis B virus (HBV)) and invasive employer or State government-required screening procedures (such as tuberculosis screening). Further, most of these

individuals met State and local vaccination requirements in order to attend school to complete the necessary education to qualify for health care positions. In addition to these longstanding vaccination requirements, many now require vaccination for COVID–19 as well. However, studies on annual seasonal influenza vaccine uptake consistently show that half of health care workers may resist seasonal influenza vaccination nationwide.[142]

Other ongoing CMS staff vaccination programs include hospital quality improvement contractors that provide educational resources to help hospitals and staff overcome vaccine hesitancy, coordinate with State health departments to support vaccine uptake (for COVID–19 and flu), and monitor staff vaccination rates for additional action. ESRD networks also provide education on patient influenza and pneumococcal vaccinations as a part of their work and also recently (in 2020) added a goal of 85 percent of patients vaccinated for flu while also encouraging vaccinations for staff within ESRD facilities. While we have not, until now, required any health care staff vaccinations, we have established, maintained, and regularly updated extensive health and safety requirements (CfCs, CoPs, requirements, etc.) for Medicare- and Medicaid-certified providers and suppliers. These requirements focus a great deal on infection prevention and control standards, often incorporating guidelines as recommended by CDC and other expert groups, as CMS's highest duty is to protect the health and safety of patients, clients, residents, and PACE program participants in all applicable settings.

The Medicare statute's various provisions authorizing the Secretary to impose requirements necessary in the interest of the health and safety of beneficiaries encompass authority to require that staff working in and for Medicare-certified providers and suppliers be vaccinated against specific diseases. In addition, parallel Medicaid statutes provide authority to establish requirements to protect beneficiary health and safety, as reflected in Table 1. We acknowledge that we have not previously imposed such requirements, but, as discussed throughout section I. of this rule, this is a unique pandemic scenario with unique access to effective vaccines. In addition, for many infectious diseases, it is not necessary for CMS to impose such requirements because other entities, including employers, states, and licensing organizations, already impose sufficient standards for those specific diseases. We believe that, given the fast-moving nature of the COVID–19 pandemic and its ongoing threat to the health and safety of individuals receiving health care services in Medicare- and Medicaid-certified providers and suppliers, our intervention is warranted. We understand that some states and localities have established laws that would seem to prevent Medicare- and Medicaid-certified providers and suppliers from complying with the requirements of this IFC. We intend, consistent with the Supremacy Clause of the United States Constitution, that this nationwide regulation preempts inconsistent State and local laws as applied to Medicare- and Medicaid-certified providers and suppliers. CDC estimates that 45.4 percent of U.S. adults are at increased risk for complications from coronavirus disease because of cardiovascular disease, diabetes, respiratory disease, hypertension, or cancer. Rates increased by age, from 19.8 percent for persons 18–29 years of age to 80.7 percent for persons >80 years of age, and varied by State, race/ethnicity, health insurance status, and employment.[143] We expect that individuals seeking health care services are more likely to fall into the high-risk category. While we do not have provider- or supplier-specific estimates, we would anticipate the percentage of high-risk individuals in health care settings is much higher than the general population. Health care consumers seeking services from the provider and suppliers included in this rule are often at significantly higher risk of severe disease and death than their paid care givers.[144] As discussed in section I.F. of this IFC, COVID–19 has disproportionally affected minority and underserved populations, who will receive safer care and better outcomes through this requirement.[145] Families, unpaid caregivers, and communities will also experience overall benefit.[146] [147] Staff will directly benefit from the protective effects of COVID–19 vaccination, but the primary reason that we are issuing this IFC requiring health care workers be vaccinated against COVID–19 is for the protection of residents, clients, patients, and PACE program participants.

I. Vaccination Requirements and Employee Protections

This IFC requires most Medicare- and Medicaid-certified providers and suppliers to ensure that their staff are fully vaccinated for COVID–19. The U.S. Equal Employment Opportunity Commission (EEOC) enforces workplace anti-discrimination laws and has established that employers can mandate COVID–19 vaccination for all employees that physically enter their facility.[148] We are expanding upon that to include all of the staff described in section II.A.1. of this IFC, for the providers and suppliers addressed by this IFC, not just those staff who perform their duties within a health care facility, as many health care staff routinely care for patients and clients outside of such facilities, such as home health, home infusion therapy, hospice, and therapy staff. In addition, there may be other times that staff encounter fellow employees, such as in an administrative office or at an off-site staff meeting, who will themselves enter a health care facility or site of care for their job responsibilities. Thus, we believe it is necessary to require vaccination for all staff that interact with other staff, patients, residents, clients, or PACE program participants in any location, beyond those that physically enter facilities or other sites of patient care.

In implementing the COVID–19 vaccination policies and procedures required by this IFC, however, employers must comply with applicable Federal anti-discrimination laws and civil rights protections. Applicable laws include: (1) The Americans with Disabilities Act (ADA); (2) Section 504 of the Rehabilitation Act (RA); (3) Title VII of the Civil Rights Act of 1964; (4) the Pregnancy Discrimination Act; and (5) the Genetic Information Nondiscrimination Act.[149] In addition, other Federal laws may provide employees with additional protections.

These Federal laws continue to apply during the PHE and, in some instances, require employers to offer

[142] Field R.I. (2009). Mandatory vaccination of health care workers: whose rights should come first? *P & T: a peer-reviewed journal for formulary management, 34*(11), 615–618.

[143] *https://wwwnc.cdc.gov/eid/article/26/8/20-0679_article.*

[144] *https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html.*

[145] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/disparities-impact.html.*

[146] *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html.*

[147] *https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html?s_cid=11509:cdc%20guidance%20delta%20variant:sem.ga:p:RG:GM:gen:PTN:FY21.*

[148] What You Should Know About COVID–19 and the ADA, the Rehabilitation Act, and Other EEO Laws. U.S. Equal Opportunity Commission. Accessed at *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.* Accessed on October 16, 2021, 2:20 p.m. EDT. Updated October 13, 2021. Section K. Vaccinations.

[149] Genetic Information Nondiscrimination Act of 2008. Public Law 110–233.

accommodations for some individual staff members in some circumstances. These laws do not interfere with or prevent employers from following the guidelines and suggestions made by CDC or public health authorities about steps employers should take to promote public health and safety in light of COVID–19, to the extent such guidelines and suggestions are consistent with the requirements set forth in this regulation. In other words, employers following CDC guidelines and the new requirements in this IFC may also be required to provide appropriate accommodations, to the extent required by Federal law, for employees who request and receive exemption from vaccination because of a disability, medical condition, or sincerely held religious belief, practice, or observance.

Vaccination against COVID–19 is a critical protective action for all individuals, especially health care workers, because the SARS-Cov-2 virus poses direct threats to patients, clients, residents, PACE program participants, and staff. COVID–19 disease at this time is resulting in much higher morbidity and mortality than seasonal flu.[150] [151] [152] These individual vaccinations provide protections to the health care system as a whole, protecting capacity and operations during disease outbreaks.

We also recognize ethical reasons to issue these vaccination requirements. All health care workers have a general ethical duty to protect those they encounter in their professional capacity.[153] Patient safety is a central tenet of the ethical codes and practice standards published by health care professional associations, licensure and certification bodies, and specialized industry groups. Health care workers also have a special ethical and professional responsibility to protect and prioritize the health and well-being of those they are caring for, as well as not exposing them to threats that can be avoided. This holds true not only for health care professionals, but also for all who provide health care services or choose to work in those settings. The ethical duty of receiving vaccinations is not new, as staff have long been required by employers to be vaccinated against certain diseases, such as influenza, hepatitis B, and other infectious diseases.

We are aware of concerns about health care workers choosing to leave their jobs rather than be vaccinated. While we understand that there might be a certain number of health care workers who choose to do so, there is insufficient evidence to quantify and compare adverse impacts on patient and resident care associated with temporary staffing losses due to mandates and absences due to quarantine for known COVID–19 exposures and illness. We encourage providers and suppliers, where possible, to consider on-site vaccination programs, which can significantly reduce barriers that health care staff may face in getting vaccinated, including transportation barriers, need to take time off of work, and scheduling. However, vaccine declination may continue to occur, albeit at lower rates, due to hesitancy among particular communities, and the Assistant Secretary for Planning and Evaluation (ASPE) indicates that vaccination promotion and outreach efforts focused on groups and communities who experience social risk factors could help address inequities.[154]

Despite these hesitations, many COVID–19 vaccination mandates have already been successfully initiated in a variety of health care settings, systems, and states. In general, workers across the economy are responding to mandates by getting vaccinated.[155] A large hospital system in Texas instituted a vaccine mandate and 99.5 percent of its staff received the vaccine. Further, only a few of their staff resigned rather than receive the vaccine.[156] A Detroit-based health system also instituted a vaccine mandate, and reported that 98 percent of the system's 33,000 workers were fully or partially vaccinated or in the process of obtaining a religious or medical exemption when the requirement went into effect, with exemptions comprising less than 1 percent of staffers.[157] In addition, a LTC parent corporation established a COVID–19 vaccine mandate for its more than 250 LTC facilities, leading to more than 95 percent of their workers being vaccinated. Again, they noted that very few workers quit their jobs rather than be vaccinated.[158] New York enacted a State-wide health care worker COVID–19 vaccine mandate and recorded a jump in vaccine compliance in the final days before the requirements took effect on October 1, 2021.[159]

We believe that the COVID–19 vaccine requirements in this IFC will result in nearly all health care workers being vaccinated, thereby benefiting all individuals in health care settings. This will greatly contribute to a reduction in the spread of and resulting morbidity and mortality from the disease, positive steps towards health equity, and an improvement in the numbers of health care staff who are healthy and able to perform their professional responsibilities. For individual staff members that have legally permitted justifications for exemption, the providers and suppliers covered by this IFC can address those individually.

II. Provisions of the Interim Final Rule With Comment Period

Through this IFC, we are requiring that the following Medicare- and Medicaid-certified providers and suppliers, listed here in order of their appearance in 42 CFR, ensure that all applicable staff are vaccinated for COVID–19:

- Ambulatory Surgical Centers (ASCs)
- Hospices
- Psychiatric residential treatment facilities (PRTFs)
- Programs of All-Inclusive Care for the Elderly (PACE)

[150] Comparison of the characteristics, morbidity, and mortality of COVID–19 and seasonal influenza: a nationwide, population-based retrospective cohort study, The Lancet, Published Online December 17, 2020 *https://doi.org/10.1016/ S2213-2600(20)30527-0.*

[151] Comparative evaluation of clinical manifestations and risk of death in patients admitted to hospital with covid–19 and seasonal influenza: cohort study, BMJ 2020;371:m4677.

[152] Klompas, M, Pearson, M, and Morris, C. The Case for Mandating COVID–19 Vaccines for Health Care Workers. Annuals of Internal Medicine. Annals.org. Accessed at *https://www.acpjournals.org/doi/10.7326/M21-2366.* Accessed on August 30, 2021. Published on July 13, 2021.

[153] Emanuel, E and Skorton, D. Mandating COVID–19 Vaccination for Health Care Workers. Annuals of Internal Medicine. Annals.org. Accessed at *https://www.acpjournals.org/doi/10.7326/M21-3150.* Accessed on August 30, 2021. Article includes the ''Joint Statement in Support of COVID–19 Vaccine Mandates for All Workers in Health and Long-Term Care'' that is signed by 80 organizations.

[154] Kolbe A. Disparities in COVID–19 vaccination rates across racial and ethnic minority groups in the United States. Washington, DC: US Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation; 2021. *https://aspe.hhs.gov/system/files/pdf/265511/vaccination-disparities-brief.pdf.*

[155] *https://theconversation.com/half-of-unvaccinated-workers-say-theyd-rather-quit-than-get-a-shot-but-real-world-data-suggest-few-are-following-through-168447.*

[156] Emanuel, E and Skorton, D. Mandating COVID–19 Vaccination for Health Care Workers. Annuals of Internal Medicine. *Annuals.org.* Accessed *https://www.acpjournals.org/doi/10.7326/M21-3150.* Accessed on August 30, 2021. Article includes the ''Joint Statement in Support of COVID–19 Vaccine Mandates for All Workers in Health and Long-Term Care'' that is signed by 88 organizations.

[157] *https://www.bridgemi.com/michigan-health-watch/despite-protests-98-henry-ford-hospital-workers-get-covid-vaccinations* accessed 09/15/2021 at 2:24 p.m. EDT.

[158] Emanuel, E and Skorton, D. Mandating COVID–19 Vaccination for Health Care Workers. Annuals of Internal Medicine. Annals.org. Accessed at *https://www.acpjournals.org/doi/10.7326/M21-3150.* Accessed on August 30, 2021. Article includes the ''Joint Statement in Support of COVID–19 Vaccine Mandates for All Workers in Health and Long-Term Care'' that is signed by 88 organizations.

[159] *https://www.nytimes.com/2021/09/28/nyregion/vaccine-health-care-workers-mandate.html.*

- Hospitals (acute care hospitals, psychiatric hospitals, long term care hospitals, children's hospitals, hospital swing beds, transplant centers, cancer hospitals, and rehabilitation hospitals)
- Long Term Care (LTC) Facilities, including SNFs and NFs, generally referred to as nursing homes
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID)
- Home Health Agencies (HHAs)
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)
- Critical Access Hospitals (CAHs)
- Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services
- Community Mental Health Centers (CMHCs)
- Home Infusion Therapy (HIT) suppliers
- Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs)
- End-Stage Renal Disease (ESRD) Facilities

For discussion purposes, we have grouped these providers and suppliers into four categories below: (1) Residential congregate care facilities; (2) acute care settings; (3) outpatient clinical care and services; and (4) home-based care. We note that the appropriate term for the individual receiving care and/or services differs depending upon the provider or supplier. For example, for hospitals and CAHs, the appropriate term is patient, but for ICFs-IID, it is client. Further, LTC facilities have residents and PACE Programs have participants. The appropriate term is used when discussing each individual provider or supplier, but when we are discussing all or multiple providers and suppliers we will use the general term ''patient.'' Similarly, despite the different terms used for specific provider and supplier entities (such as campus, center, clinic, facility, organization, or program), when we are discussing all or multiple providers and suppliers, we will use the general term ''facility.''

A. Provisions of the Interim Final Rule With Comment Period

In this IFC, we are issuing a common set of provisions for each applicable provider and supplier. As there are no substantive regulatory differences across settings, we discuss the provisions broadly in this section of the rule, along with their rationales. In subsequent sections of the rule we discuss any unique considerations for each setting.

1. Staff Subject to COVID–19 Vaccination Requirements

The provisions of this IFC require applicable providers and suppliers to develop and implement policies and procedures under which all staff are vaccinated for COVID–19. Each facility's COVID–19 vaccination policies and procedures must apply to the following facility staff, regardless of clinical responsibility or patient contact and including all current staff as well as any new staff, who provide any care, treatment, or other services for the facility and/or its patients: Facility employees; licensed practitioners; students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement. These requirements are not limited to those staff who perform their duties within a formal clinical setting, as many health care staff routinely care for patients and clients outside of such facilities, such as home health, home infusion therapy, hospice, PACE programs, and therapy staff. Further, there may be staff that primarily provide services remotely via telework that occasionally encounter fellow staff, such as in an administrative office or at an off-site staff meeting, who will themselves enter a health care facility or site of care for their job responsibilities. Thus, we believe it is necessary to require vaccination for all staff that interact with other staff, patients, residents, clients, or PACE program participants in any location, beyond those that physically enter facilities, clinics, homes, or other sites of care. Individuals who provide services 100 percent remotely, such as fully remote telehealth or payroll services, are not subject to the vaccination requirements of this IFC.

In the May 13, 2021 COVID–19 IFC, we included an extensive discussion on the subject of ''staff'' in relation to the LTC facility staff and to whom the testing, reporting, and education and offering of COVID–19 vaccine requirements of that rule might apply. In that discussion, we considered LTC facility staff to be those individuals who work in the facility on a regular (that is, at least once a week) basis. We note that this includes those individuals who may not be physically in the LTC facility for a period of time due to illness, disability, or scheduled time off, but who are expected to return to work. We also note that this description of staff differs from that in § 483.80(h), established for the LTC facility COVID–19 testing requirements in the September 2, 2020 COVID–19 IFC. As in the May 13, 2021 COVID–19 IFC, we considered applying the § 483.80(h) definition to the staff vaccination requirements in this rule, but previous public feedback and our own experience tells us the definition in § 483.80(h) was overbroad for these purposes.

Stakeholders across settings have reported that there are many individuals providing occasional health care services under arrangement, and that the requirements may be excessively burdensome for facilities to apply the definition at § 483.80(h) because it includes many individuals who have very limited, infrequent, or even no contact with facility staff and residents. Stakeholders also report that applying the staff vaccination requirements to these individuals who may only make unscheduled visits to the facility would be extremely burdensome. That said, the description in this rule still includes many of the individuals included in § 483.80(h). In addition to facility-employed staff, many facilities have services provided directly, on a regular basis, by individuals under contract or arrangement, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, social workers, and portable x-ray suppliers. Any of these individuals who provide such health care services at a facility would be included in ''staff'' for whom COVID–19 vaccination is now required as a condition for continued provision of those services for the facility and/or its patients.

In order to best protect patients, families, caregivers, and staff, we are not limiting the vaccination requirements of this IFC to individuals who are present in the facility or at the physical site of patient care based upon frequency. Regardless of frequency of patient contact, the policies and procedures must apply to all staff, including those providing services in home or community settings, who directly provide any care, treatment, or other services for the facility and/or its patients, including employees; licensed practitioners; students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement. This includes administrative staff, facility leadership, volunteer or other fiduciary board members, housekeeping and food services, and others. We considered excluding individual staff members who are present at the site of care less frequently than once per week from these vaccination requirements, but were concerned that this might lead to

confusion or fragmented care. Therefore, any individual that performs their duties at any site of care, or has the potential to have contact with anyone at the site of care, including staff or patients, must be fully vaccinated to reduce the risks of transmission of SARS–CoV–2 and spread of COVID–19.

Facilities that employ or contract for services by staff who telework full-time (that is, 100 percent of their time is remote from sites of patient care, and remote from staff who do work at sites of care) should identify and monitor these individuals as a part of implementing the policies and procedures of this IFC, documenting and tracking overall vaccination status, but those individuals need not be subject to the vaccination requirements of this IFC. Note, however, that these individuals may be subject to other Federal requirements for COVID–19 vaccination.

We recognize that many infrequent services and tasks performed in or for a health care facility are conducted by ''one off'' vendors, volunteers, and professionals. Providers and suppliers are not required to ensure the vaccination of individuals who infrequently provide ad hoc non-health care services (such as annual elevator inspection), or services that are performed *exclusively off-site,* not at or adjacent to any site of patient care (such as accounting services), but they may choose to extend COVID–19 vaccination requirements to them if feasible. Other individuals who may infrequently enter a facility or site of care for specific limited purposes and for a limited amount of time, but do not provide services by contract or under arrangement, may include delivery and repair personnel.

We believe it would be overly burdensome to mandate that each provider and supplier ensure COVID–19 vaccination for all individuals who enter the facility. However, while facilities are not required to ensure vaccination of every individual, they may choose to extend COVID–19 vaccination requirements beyond those persons that we consider to be staff as defined in this rulemaking. We do not intend to prohibit such extensions and encourage facilities to require COVID–19 vaccination for these individuals as reasonably feasible.

When determining whether to require COVID–19 vaccination of an individual who does not fall into the categories established by this IFC, facilities should consider frequency of presence, services provided, and proximity to patients and staff. For example, a plumber who makes an emergency repair in an empty restroom or service area and correctly wears a mask for the entirety of the visit may not be an appropriate candidate for mandatory vaccination. On the other hand, a crew working on a construction project whose members use shared facilities (restrooms, cafeteria, break rooms) during their breaks would be subject to these requirements due to the fact that they are using the same common areas used by staff, patients, and visitors. Again, we strongly encourage facilities, when the opportunity exists and resources allow, to facilitate the vaccination of all individuals who provide services infrequently and are not otherwise subject to the requirements of this IFC.

2. Determining When Staff Are Considered ''Fully Vaccinated''

In consideration of the different vaccines available for COVID–19, we require that providers and suppliers ensure that staff are fully vaccinated for COVID–19, which, for purposes of these requirements, is defined as being 2 weeks or more since completion of a primary vaccination series. This definition of ''fully vaccinated'' is consistent with the CDC definition. Additionally, the completion of a primary vaccination series for COVID–19 is defined in the requirements as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

We note that the concept of a ''primary series'' is commonly understood with respect to vaccinations, particularly among health care professionals as well as the providers and suppliers regulated by this rule. For purposes of this IFC, and if permitted or recommended by CDC, COVID–19 vaccine doses from different manufacturers may be combined to meet the requirements for a primary vaccination series.

We further note that recommendations for booster doses currently vary by vaccine and population, and expect that they will continue to vary for the foreseeable future. We also require that providers and suppliers must have a process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC. Additionally, some staff members may have been vaccinated during participation in a clinical trial, or in countries other than the U.S. We discuss the applicability of these less common vaccination pathways in section I.B. of this IFC.

Currently, for two of the three vaccines licensed or authorized for use in the U.S., the primary vaccination series consists of a defined number of doses administered a certain number of weeks apart; therefore, we have made this particular requirement effective in two different phases. We discuss these implementation phases further in section II.B. of this IFC, but note here that Phase 1, effective 30 days after publication of this IFC, includes the requirement that staff receive the first dose, or only dose as applicable, of a COVID–19 vaccine, or have requested or been granted an exemption to the vaccination requirements of this IFC. Phase 2, effective 60 days after publication of this IFC, requires that the primary vaccination series has been completed and that staff are fully vaccinated, except for those staff have been granted exemptions, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by CDC, due to clinical precautions and considerations. As discussed in section II.B. of this IFC, staff who have completed the primary series for the vaccine received by the Phase 2 implementation date are considered to have met these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination.

3. Infection Prevention and Control

We require through this IFC that all applicable providers and suppliers have a process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19. While every health care facility should be following recommended infection control and prevention measures as recommended by CDC as part of their provision of safe health care services, not all of the providers and suppliers subject to the requirements of this IFC have specific infection control and prevention regulations in place. Specifically, there are no infection prevention and control requirements for PRTFs, RHCs/FQHCs, and HIT suppliers. Therefore, for PRTFs, RHCs/FQHCs, and HIT suppliers, we require that they have a process for ensuring that they follow nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID–19. This process must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID–19. For the providers and suppliers included in this IFC that are already subject to meeting specific infection prevention and control requirements on

an ongoing basis, we require that they have a process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19.

4. Documentation of Staff Vaccinations

In order to ensure that providers and suppliers are complying with the vaccination requirements of this IFC, we are requiring that they track and securely document the vaccination status of each staff member, including those for whom there is a temporary delay in vaccination, such as recent receipt of monoclonal antibodies or convalescent plasma. Vaccine exemption requests and outcomes must also be documented, discussed further in section II.A.5. of this IFC. This documentation will be an ongoing process as new staff are onboarded.

While provider and supplier staff may not have personal medical records on file with their employer, all staff COVID–19 vaccines must be appropriately documented by the provider or supplier. Examples of appropriate places for vaccine documentation include a facilities immunization record, health information files, or other relevant documents. All medical records, including vaccine documentation, must be kept confidential and stored separately from an employer's personnel files, pursuant to ADA and the Rehabilitation Act.

Examples of acceptable forms of proof of vaccination include:

- CDC COVID–19 vaccination record card (or a legible photo of the card),
- Documentation of vaccination from a health care provider or electronic health record, or
- State immunization information system record.

If vaccinated outside of the U.S., a reasonable equivalent of any of the previous examples would suffice.

Providers and suppliers have the flexibility to use the appropriate tracking tools of their choice. For those who would like to use it, CDC provides a staff vaccination tracking tool that is available on the NHSN website (*https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html*). This is a generic Excel-based tool available for free to anyone, not just NHSN participants, that facilities can use to track COVID–19 vaccinations for staff members.

5. Vaccine Exemptions

While nothing in this IFC precludes an employer from requiring employees to be fully vaccinated, we recognize that there are some individuals who might be eligible for exemptions from the COVID–19 vaccination requirements in this IFC under existing Federal law. Accordingly, we require that providers and suppliers included in this IFC establish and implement a process by which staff may request an exemption from COVID–19 vaccination requirements based on an applicable Federal law. Certain allergies, recognized medical conditions, or religious beliefs, observances, or practices, may provide grounds for exemption. With regard to recognized clinical contraindications to receiving a COVID–19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID–19 Vaccines Currently Authorized in the United States,* accessed at *https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf*.

As described in section I.I. of this IFC, there are Federal laws, including the ADA, section 504 of the Rehabilitation Act, section 1557 of the ACA, and Title VII of the Civil Rights Act, that prohibit discrimination based on race, color, national origin, religion, disability and/or sex, including pregnancy. We recognize that, in some circumstances, employers may be required by law to offer accommodations for some individual staff members. Accommodations can be addressed in the provider or supplier's policies and procedures.

Applicable staff of the providers and suppliers included in this IFC must be able to request an exemption from these COVID–19 vaccination requirements based on an applicable Federal law, such as the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964. Providers and suppliers must have a process for collecting and evaluating such requests, including the tracking and secure documentation of information provided by those staff who have requested exemption, the facility's decision on the request, and any accommodations that are provided.

Requests for exemptions based on an applicable Federal law must be documented and evaluated in accordance with applicable Federal law and each facility's policies and procedures. As is relevant here, this IFC preempts the applicability of any State or local law providing for exemptions to the extent such law provides broader exemptions than provided for by Federal law and are inconsistent with this IFC.

For staff members who request a medical exemption from vaccination, all documentation confirming recognized clinical contraindications to COVID–19 vaccines, and which supports the staff member's request, must be signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws. Such documentation must contain all information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and a statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID–19 vaccination requirements based on the recognized clinical contraindications.

Under Federal law, including the ADA and Title VII of the Civil Rights Act of 1964 as noted previously, workers who cannot be vaccinated or tested because of an ADA disability, medical condition, or sincerely held religious beliefs, practice, or observance may in some circumstances be granted an exemption from their employer. In granting such exemptions or accommodations, employers must ensure that they minimize the risk of transmission of COVID–19 to at-risk individuals, in keeping with their obligation to protect the health and safety of patients. Employers must also follow Federal laws protecting employees from retaliation for requesting an exemption on account of religious belief or disability status. For more information about these situations, employers can consult the Equal Employment Opportunity Commission's website at *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws*.

We also direct providers and suppliers to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination [160] for information on evaluating and responding to such requests. While employers have the flexibility to establish their own processes and procedures, including forms, we point to The Safer Federal Workforce Task Force's ''request for a religious exception to the COVID–19 vaccination requirement'' template as an example. This template can be viewed at *https://*

[160] *https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination.*

www.saferfederalworkforce.gov/downloads/RELIGIOUS%20REQUEST%20FORM%20-%2020211004%20-%20MH508.pdf.

6. Planning

Despite the near-universal applicability of the requirements described in sections II.A.1. through 5 of this IFC, we recognize that the course of the COVID–19 pandemic remains unpredictable. Due to likely unforeseen circumstances, we require that providers and suppliers make contingency plans in consideration of staff that are not fully vaccinated to ensure that they will soon be vaccinated and will not provide care, treatment, or other services for the provider or its patients until such time as such staff have completed the primary vaccination series for COVID–19 and are considered fully vaccinated, or, at a minimum, have received a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine. This planning should also address the safe provision of services by individuals who have requested an exemption from vaccination while their request is being considered and by those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations.

While the nature of this rulemaking suggests the potential that virtually all health care staff in the U.S. will be vaccinated for COVD–19 within a matter of months, local outbreaks, new viral variations, changes in disease manifestation, or other factors necessitate contingency planning. Contingency planning may extend beyond the specific requirements of this rule to address topics such as staffing agencies that can supply vaccinated staff if some of the facility's staff are unable to work. Contingency plans might also address special precautions to be taken when, for example, there is a regional or local emergency declaration, such as for a hurricane or flooding, which necessitates the temporary utilization of unvaccinated staff, in order to assure the safety of patients. For example, expedient evacuation of a flooding LTC facility may require assistance from local community members of unknown vaccination status. Facilities may already have contingency plans that meet the requirements of this IFC in their existing Emergency Preparedness policies and procedures.

B. Implementation Dates

Due to the urgent nature of the vaccination requirements established in this IFC, we have not issued a proposed rule, as discussed in section III. of this IFC. While some IFCs are effective immediately upon publication, we understand that instantaneous compliance, or compliance within days, with these regulations is not possible. Vaccination requires time, especially those vaccines delivered in a series, and facilities may wish to coordinate scheduling of staff vaccination appointments in a staggered manner so that appropriate coverage is maintained. The policies and procedures required by the IFC will also take time for facilities to develop. However, in order to provide protection to residents, patients, clients, and PACE program participants (as applicable), we believe it is necessary to begin staff vaccinations as quickly as reasonably possible.

In order to provide protection as soon as possible, we are establishing two implementation phases for this IFC. Phase 1, effective 30 days after publication, includes nearly all provisions of this IFC, including the requirements that all staff have received, at a minimum, the first dose of the primary series or a single dose COVID–19 vaccine, or requested and/or been granted a lawful exemption, prior to staff providing any care, treatment, or other services for the facility and/or its patients. Phase 1 also includes the requirements for facilities to have appropriate policies and procedures developed and implemented, and the requirement that all staff must have received a single dose COVID–19 vaccine or the initial dose of a primary series by December 6, 2021.

Phase 2, effective 60 days after publication, consists of the requirement that all applicable staff are fully vaccinated for COVID–19, except for those staff who have been granted exemptions from COVID–19 vaccination or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations). Although an individual is not considered fully vaccinated until 14 days (2 weeks) after the final dose, staff who have received the final dose of a primary vaccination series by the Phase 2 effective date are considered to have meet the individual vaccination requirements, even if they have not yet completed the 14-day waiting period. For example, an individual may receive the first dose of the Moderna mRNA COVID–19 Vaccine 2 or 3 days prior to the Phase 1 deadline, but must wait at least 28 days before receiving the second dose. This second dose could (and must, for purposes of this IFC) be administered prior to the Phase 2 effective date, but the individual would still be subject to meeting additional precautions as described in section II.A.3. of this IFC until 14 days had passed. This timing flexibility applies only to the initial implementation of this IFC and has no bearing on ongoing compliance. This information is also presented in Table 2.

TABLE 2: Effective Dates

	Date	New Regulatory Provisions	Corresponding Citations (42 CFR)
Phase 1	December 6, 2021	For all providers and suppliers included in this IFC, all requirements except the requirement for completion of a primary vaccination series for COVID-19.	All other provisions of this IFC, except those in Phase 2 at: § 416.51(c) § 418.60(d) § 441.151(c) § 460.74(d) § 482.42(g) § 483.80(d)(3)(v) and 483.80(i) § 483.430(f) § 483.460(a)(4)(v) § 484.70(d) § 485.58(d)(4) and 485.70(n) § 485.640(f) § 485.725(f) § 485.904(c) § 486.525(c) § 491.8(d) § 494.30(b)
Phase 2	January 4, 2022	For all providers and suppliers included in this IFC, the requirement for ensuring that all staff have completed the primary vaccination series for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or who have not completed the primary series for the vaccine received (including those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations). Staff who have completed the primary vaccination series by this date are considered to meet these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination.	§ 416.51(c)(3)(ii) § 418.60(d)(3)(ii) § 441.151(c)(3)(ii) § 460.74(d)(3)(ii) § 482.42(g)(3)(ii) § 483.80(i)(3)(ii) § 483.430(f)(3)(ii) § 484.70(d)(3)(ii) § 485.70(n)(3)(ii) § 485.640(f)(3)(ii) § 485.725(f)(3)(ii) § 485.904(c)(3)(ii) § 486.525(c)(3)(ii) § 491.8(d)(3)(ii) § 494.30(b)(3)(ii)

We note that although this IFC is being issued in response to the PHE for COVID–19, we expect it to remain relevant for some time beyond the end of the formal PHE. Depending on the future nature of the COVID–19 pandemic, we may retain these provisions as a permanent requirement for facilities, regardless of whether the Secretary continues the ongoing PHE declarations. Therefore, this rulemaking's effectiveness is not associated with or tied to the PHE declarations, nor is there a sunset clause. Pursuant to section 1871(a)(3) of the Act, Medicare interim final rules expire 3 years after issuance unless finalized. We expect to make a determination based on public comments, incidence, disease outcomes, and other factors regarding whether it will be necessary to conduct final rulemaking and make this rule permanent.

C. Enforcement

As we do with all new or revised requirements, CMS will issue interpretive guidelines, which include survey procedures, following publication of this IFC. We will advise and train State surveyors on how to assess compliance with the new requirements among providers and suppliers. For example, the guidelines will instruct surveyors on how to determine if a provider or supplier is compliant with the requirements by reviewing the entity's records of staff vaccinations, such as a list of all staff and their individual vaccination status or qualifying exemption. The guidelines will also instruct surveyors to conduct interviews staff to verify their vaccination status. Furthermore, the entity's policy and procedures will be reviewed to ensure each component of the requirement has been addressed. We will also provide guidance on how surveyors should cite providers and suppliers when noncompliance is identified. Lastly, providers and suppliers that are cited for noncompliance may be subject to enforcement remedies imposed by CMS depending on the level of noncompliance and the remedies available under Federal law (for example, civil money penalties, denial of payment for new admissions, or termination of the Medicare/Medicaid provider agreement). CMS will closely monitor the status of staff vaccination rates, provider compliance, and any other potential risks to patient, resident, client, and PACE program participant health and safety.

D. Residential Congregate Care Facilities

Individuals residing in congregate care settings such as LTC facilities, intermediate care facilities for individuals with intellectual disabilities (ICFs-IID), and psychiatric residential treatment facilities for individuals under 21 years of age (PRTFs), regardless of health or medical conditions, are at greater risk of acquiring infections. This higher risk applies to most bacterial and viral infections, including SARS–CoV–2. Staff working in these facilities often work across facility types (that is, LTC facilities, group homes, assisted living facilities, in home and community-based services settings, and even different congregate settings within the employer's purview), and for different providers, which may contribute to virus transmission. Other factors impacting virus transmission in these settings might include: Clients or residents who are employed outside the congregate living setting; clients or residents who require close contact with staff or direct service providers; clients or residents who have difficulty understanding information or practicing preventive measures; and clients or residents in close contact with each other in shared living or working spaces.

1. Long Term Care Facilities (Skilled Nursing Facilities and Nursing Facilities)

Long term care (LTC) facilities, a category that includes Medicare skilled nursing facilities (SNFs) and Medicaid nursing facilities (NFs), also collectively called nursing homes, must meet the consolidated Medicare and Medicaid requirements for participation (requirements) for LTC facilities (42 CFR part 483, subpart B) that were first published in the **Federal Register** on February 2, 1989 (54 FR 5316). These regulations have been revised and added to since that time, principally as a result of legislation or a need to address specific issues. The requirements were comprehensively revised and updated in October 2016 (81 FR 68688), including a comprehensive update to the requirements for infection prevention and control.

CMS establishes requirements for acceptable quality in the operation of health care entities. LTC facilities are required to comply with the requirements in 42 CFR part 483, subpart B, to receive payment under the Medicare or Medicaid programs. In addition to several discrete requirements set out under sections 1819 and 1919 of the Act, Medicare- and Medicaid-participating LTC facilities ''must meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary.'' [161] More specifically, the infection control requirements for LTC facilities are based on sections 1819(d)(3)(A) (for skilled nursing facilities) and 1919(d)(3)(A) (for nursing facilities) of the Act, which both require that a facility establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment in which residents reside and to help prevent the development and transmission of disease and infection.

Since the onset of the PHE, we have revised the requirements for LTC facilities through three IFCs focused on COVID–19 testing, data reporting and vaccine requirements for residents and staff. Specifically, we have published the following IFCs:

- The first IFC, ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (FR27550) was published on May 8, 2020. The May 8, 2020 COVID–19 IFC established requirements for LTC facilities to report information related to COVID–19 cases among facility residents and staff, we received 299 public comments. About 161, or over one-half of those comments, addressed the requirement for COVID–19 reporting for LTC facilities set forth at § 483.80(g).
- The second IFC, ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (FR54873) was published on September 2, 2020. The September 2, 2020 COVID–19 IFC strengthened CMS' ability to enforce compliance with LTC facility reporting requirements and established a new requirement for LTC facilities to test facility residents and staff for COVID–19. We received 171 public comments in response to the September 2, 2020 COVID–19 IFC, of which 113 addressed the requirement for COVID–19 testing of LTC facility residents and staff set forth at § 483.80(h).
- The third IFC, ''Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff'' (86FR26306) was published on May 13, 2021. We received 71 public comments in response to the May 13, 2021 COVID–19 IFC, of which most addressed the requirements for COVID–19 educating, offering, and reporting of the uptake of COVID–19 vaccine for LTC facility residents and staff set forth at §§ 483.80(d)(3) and 483.80(g)(1). In that rule, we also required the educating, offering, and recommended voluntary reporting of COVID–19 vaccine uptake in ICFs-IID facility clients and staff set forth at §§ 483.430, Facility Staffing requirements, and 483.460, Health Care Services for Clients.

Under § 483.80(d)(3), as established in the May 13, 2021 IFC, we require LTC facilities to educate residents and staff on the COVID–19 vaccines and also to offer the vaccine, when available, to all residents and staff. The May 13, 2021 IFC also required LTC facilities to report both resident and staff vaccine uptake and status to CDC's National Healthcare Safety Network (NHSN) (§ 483.80(d)(3)(vii)); this has been a requirement since May 21, 2021. The CDC data collected under this requirement show that vaccination rates for LTC facility staff have stalled, with a 64 percent national average of vaccinated staff according to CDC data as of August 28, 2021, while the number of new LTC facility resident COVID–19 cases reported per week has risen by just over 1455 percent from recorded lows in June 2021 (323 cases in the week ending June 27, 2021; 4701 in the week ending August 22, 2021). There is wide variation among states in staff vaccination rates.

With this IFC, we are amending the requirements at § 483.80, Infection Control, by revising paragraph (d)(3)(v) by deleting the words, ''or a staff member,'' and adding the word, ''or'' before ''resident representative,'' so that the provision now reads, ''the resident, or resident representative, has the opportunity to accept or refuse a COVID–19 vaccine, and change their decision.'' Retaining the language permitting staff to refuse vaccination would be inconsistent with the goals of this IFC. We are further amending the requirements at § 483.80 to add a new paragraph (i), titled ''COVID–19 Vaccination of facility staff,'' to specify that facilities must now develop and implement policies and procedures to ensure that all staff are fully

[161] Section 1819(d)(4)(B) of the Act. Section 1919(d)(4)(B) is nearly identical, but omitting ''well-being''.

vaccinated—that is, staff for whom it has been 2 weeks or more since they completed a primary vaccination series for COVID–19, with the completion of a primary vaccination series for COVID–19 defined as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

For this rule, we have also added a new paragraph at § 483.80(i)(2), which specifies which staff for whom the requirements for staff COVID–19 vaccination will not apply: (1) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with residents and other staff (for whom the requirements do apply) and (2) staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with residents and other staff (for whom the requirements do apply).

Additionally, under the requirements of this IFC, we are adding § 483.80(i)(3) to now require that a facility's policies and procedures for COVID–19 vaccination of staff must include, at a minimum, the components specified in section II.A. of this IFC. New §§ 483.80(i)(3)(i) through (x) specify these required minimum components of the facility's policies and procedures.

2. Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID)

ICFs-IID are residential facilities that provide services for people with intellectual disabilities. ICF–IID clients with certain underlying medical or psychiatric conditions may be at increased risk of serious illness from COVID–19.[162] On March 2, 2021, CDC issued Interim Considerations for Phased Implementation of COVID–19 Vaccination and Sub Prioritization Among Recommended Populations, which notes that increased rates of transmission have been observed in these settings, and that jurisdictions may choose to prioritize vaccination of persons living in congregate settings based on local, State, tribal, or territorial epidemiology. CDC further notes that congregate living facilities may choose to vaccinate residents and clients at the same time as staff, due to numerous factors, such as convenience or shared increased risk of disease.

Sections 1905(c) and (d) of the Act gave the Secretary authority to prescribe regulations for intermediate care facility services in facilities for individuals with intellectual disabilities or persons with related conditions. The ICFs-IID Conditions of Participation were issued on June 3, 1988 (53 FR 20496) and were last updated on May 13, 2021 (86 FR 20448). There are currently 5,768 Medicare- and/or Medicaid-certified ICFs-IID. As of April 2021, 4,661 of the 5,770 are small (1 to 8 beds) in size, but there are 1,107 that are larger (14 or more beds) facilities. These facilities serve over 64,812 individuals with intellectual disabilities and other related conditions. All must qualify for Medicaid coverage. While national data about ICFs-IID clients is limited, we take an example from Florida where almost one quarter of clients (23 percent) require 24-hour nursing services and a medical care plan in addition to their services plans.[163] Data from a single State are not nationally representative and thus we are unable to generalize, but it is illustrative.

Currently, the Conditions of Participation: ''Health Care Services'' at § 483.460(a)(4)(i) require that ICFs-IID offer clients and staff vaccination against COVID–19 when vaccine supplies are available (86 FR 26306). Based on anecdotal reports, this new requirement has not significantly increased vaccination among ICFs-IID staff. We conclude that additional regulatory action is necessary to achieve widespread vaccination among ICFs-IID staff to protect ICFs-IID clients.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 483.430(g) related to establishing and implementing policies and procedures for COVID–19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

3. Psychiatric Residential Treatment Facilities (PRTFs)

PRTFs are non-hospital facilities that provide inpatient psychiatric services to Medicaid-eligible individuals under the age of 21 (also called the ''psych under 21 benefit''). There are 357 PRTFs in the U.S. The facilities must meet accreditation standards, the requirements in §§ 441.151 through 441.182, and the Condition of Participation on the use of restraint and seclusion at § 483.350 through § 483.376.

Among the requirements for the psych under 21 benefit are certification of need for inpatient care and a plan of care for active treatment developed by an interdisciplinary team. The psych under 21 benefit is significant as a means for Medicaid to cover the cost of inpatient behavioral health services. The Federal Medicaid program does not reimburse states for the cost of covered services provided to beneficiaries in institutions for mental diseases (IMDs) except in specific, statutorily-authorized exceptions, including for young people who receive this service, and individuals age 65 or older served in an IMD. A PRTF provides comprehensive behavioral health treatment to children and adolescents (youth) who, due to mental illness, substance use disorders, or severe emotional disturbance, need treatment that can most effectively be provided in a residential treatment facility. PRTF programs are designed to offer a short term, intense, focused behavioral health treatment program to promote a successful return of the youth to the community.

As a congregate living setting, PRTFs are subject to many of the same elevated transmission risk factors as LTC facilities and ICFs-IID as set forth in section I. of this IFC. Section 1905(h) of the Act defines inpatient psychiatric hospital services for individuals under 21 as any inpatient facility that the Secretary has prescribed in regulations that in the case of any individual involve active treatment which meets such standards as may be prescribed in regulations by the Secretary. Implementing essential infection control practices, including vaccination, is a basic infection control treatment standard.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 441.151(c) related to establishing and implementing policies and procedures for COVID–19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its clients.

E. Acute Care Settings

Acute care settings are those providers who generally provide active care for short-term medical needs. For our discussion purposes acute care settings include: Hospitals, critical access hospitals (CAHs), and ambulatory surgical centers (ASCs).

1. Hospitals

Hospitals are large health care providers that treat patients with acute

[162] *https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html.*

[163] *http://www.floridaarf.org/assets/Files/ICF-IID%20Info%20Center/ICFHandoutonWebsite2-14.pdf.*

care needs including emergency medicine, surgery, labor and delivery, cardiac care, oncology, and a wide variety of other services. Hospitals also administer general and specialty care that cannot safely be provided in other settings, under the supervision of physicians and licensed practitioners. They may operate as independent institutions or as part of a larger health care system or learning institution.

Section 1861(e) of the Act provides that hospitals participating in Medicare and Medicaid must meet certain specified requirements, and the Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals. Medicare-participating hospitals, which include nearly all hospitals in the U.S., must meet the Conditions of Participation (CoPs) at 42 CFR part 482, originally issued June 17, 1986. In addition to smaller updates over the years, these CoPs were reformed in 2012 (77 FR 29034). Hospital CoPs identify infection control and prevention as a basic hospital function and lay out specific requirements at 42 CFR 482.42. Infection control within a hospital campus is especially important, because hospitals treat individuals with infectious diseases (such as COVID–19) and healthy yet higher-risk individuals (for example, pregnant and post-partum individuals, infants, transplant recipients, etc.) within the same facility. Hospitals that provide emergency care must do so in accordance with the requirements of the Emergency Medical Treatment and Labor Act (EMTALA) of 1986.

Hospitals have borne the brunt of caring for patients with acute COVID–19 during the PHE. Individuals experiencing respiratory problems, cardiac events, kidney failure, and other serious effects of COVID–19 illness have required in-hospital care in large numbers, to the point of occupying or even exceeding most or all critical care or ICU capacity in a facility, city, or region. Despite emergency expansion of critical care units, these waves of severely ill patients have overwhelmed hospitals, health care systems, and the professionals and other staff who work in them. This has had the disastrous effect of limiting access and increasing risk to both routine and emergency hospital care across the U.S.[164] [165] [166] [167]

Transplant centers, psychiatric hospitals, and swing beds are governed by the infection control CoPs for hospitals, and are thus subject to the staff vaccination requirements issued in this IFC. We are particularly concerned about transplant center patients, who are among the most severely immunocompromised individuals due to anti-rejection medications that ensure the function of transplanted organs. An additional member of the transplant ecosystem, Organ Procurement Organizations (OPOs) coordinate and support donation, recovery, and placement of organs. As OPO staff do not provide patient care, and typically work in locations removed from health care facilities, we are not issuing vaccination requirements for OPOs in this IFC. That said, we note that the vaccination policies required in this IFC apply to all individuals who provide care, treatment, or other services for the hospital and/or its patients, under contract or other arrangement. Accordingly, OPO staff members that provide organ transplantation services directly to hospital and transplant center patients and families must meet the vaccination requirements of this IFC.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 482.42(g) related to establishing and implementing policies and procedures for COVID–19 vaccination of all staff (including employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

2. Critical Access Hospitals (CAHs)

CAHs are rural hospitals that have been designated as critical access hospitals by the State, in a State that has established a State Medicare Rural Hospital Flexibility Program. These hospitals have 25 or fewer acute care inpatient beds (except as permitted for CAHs having distinct part units under § 485.647, where the beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in § 485.620(a)), must be more than 35 miles away from another hospital, and provide emergency care services 24 hours a day, 7 days a week. On average, acute patients stay in CAHs for less than 96 hours. CAHs may be granted approval to provide post-hospital skilled nursing care, may offer hospice care under the Medicare hospice benefit, and may operate a psychiatric and/or rehabilitation distinct part unit of up to 10 beds each. CAHs also administer general and specialty care that cannot safely be provided in other settings, under the supervision of physicians and licensed practitioners. They may operate as independent institutions or as part of a larger health care system. Generally, they serve to help ensure access to health-care services in rural communities.

Section 1820 of the Act sets forth the conditions for certifying a facility as a CAH to include meeting such other criteria as the Secretary may require. Medicare-certified CAHs must meet the Conditions of Participation (CoPs) at 42 CFR part 485 subpart F, originally issued May 26, 1993 (58 FR 30630). These CoPs contain specific requirements for infection control and prevention at § 485.640. Much like a standard hospital, infection control within a CAH is especially important, because CAHs treat individuals with infectious diseases (such as COVID–19) and healthy yet higher-risk individuals (for example, pregnant and post-partum individuals, infants, transplant recipients, etc.) within the same facility.

While organ transplants are not performed in CAHs, we note that organ donors may be CAH patients, and organ donation and recovery may occur in CAHs. We note that the vaccination policies required in this IFC apply to all individuals who provide care, treatment, or other services for the hospital and/or its patients, under contract or other arrangement. Accordingly, OPO staff members that provide organ donation and transplantation services directly to CAH patients and families must meet the vaccination requirements of this IFC in the same manner as they meet such requirements for hospitals.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 485.640(f) related to establishing and implementing policies and procedures for COVID–19 vaccination of all staff (including employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

3. Ambulatory Surgical Centers (ASCs)

ASCs are distinct entities that operate exclusively for the purpose of providing surgical services to patients not requiring hospitalization, and in which the expected duration of services would not exceed 24 hours following an

[164] *https://www.nytimes.com/live/2021/09/23/world/covid-delta-variant-vaccine#covid-alaska-hospital,* accessed 10/18/2021.

[165] *https://www.healthline.com/health-news/how-surging-delta-variant-is-leading-to-rationed-care-at-hospitals,* accessed 10/18/2021.

[166] *https://www.aamc.org/news-insights/worst-surge-we-ve-seen-some-hospitals-delta-hot-spots-close-breaking-point,* accessed 10/18/2021.

[167] *https://www.washingtonpost.com/health/2021/08/18/covid-hospitals-delta/,* accessed 10/18/2021.

admission. The surgical services performed in ASCs generally are scheduled, non-life-threatening procedures that can be safely performed in either a hospital setting (inpatient or outpatient) or in an ASC. Currently, there are 6,071 Medicare-certified ASCs in the U.S.

Section 1833(i)(1)(A) of the Act authorizes the Secretary to specify those surgical procedures that can be performed safely in an ASC. Section 1832(a)(2)(F)(i) of the Act defines an ASC as a facility ''which meets health, safety, and other standards specified by the Secretary in regulations . . .''.

The ASC Conditions for Coverage (CfCs) at 42 CFR part 416, subpart C, are the minimum health and safety standards a center must meet to obtain Medicare certification. The ASC CfCs were issued on August 5, 1982 (47 FR 34082), and the Conditions related to infection control were last updated on November 18, 2008 (73 FR 68502, 68813). Section 416.51, Infection control, requires ASCs to maintain an infection control program that seeks to minimize infections and communicable diseases. In this IFC we are adding new § 416.51(c) which requires ASCs to meet the same COVID–19 vaccination of staff requirements as those we are issuing for the other providers and suppliers identified in this rule.

During the COVID–19 pandemic and PHE, hospitals moved many non-elective surgical procedures to ASCs and other outpatient settings. Such movement conserves hospital resources for treating severe COVID–19, performing more urgent procedures, and caring for patients with more critical health needs. Moreover, referring patients in need of suitable procedures to ASCs limits the overall number of individuals visiting the hospital setting, thereby inhibiting spread of infection. ASCs also offer an alternative setting for outpatient surgery for individuals reluctant to enter a hospital due to fears of COVID–19 exposure. Based on these and other factors, the demand for ASC services has increased.[168]

In response to the COVID–19 pandemic, ASCs assumed new roles. CMS's Hospital Without Walls initiative permitted hospitals to provide inpatient care in ASCs and other temporary sites. ASCs have assisted with COVID–19 testing. They provided staff to work in COVID–19 hot spots. These efforts illustrate that staff and patients of ASCs regularly interact with staff and patients of other health care organizations and facilities.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 416.51(c) related to establishing and implementing policies and procedures for COVID–19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

F. Outpatient Clinical Care & Services

These clinical settings provide necessary, ongoing care for individuals who need ongoing therapeutic, and in some cases life-sustaining, care. While many of these settings have been able to provide some services safely and effectively via telehealth during the PHE, many of the services they provide require patients and clients to see staff in person.

1. End-Stage Renal Disease (ESRD) Facilities

ESRD facilities provide a set of life-sustaining services to individuals without kidney function, including dialysis, medication, routine evaluations and monitoring, nutritional counselling, social support, and organ transplantation evaluation and referral. Section 1881(b)(1)(A) of the Act authorizes the Secretary to pay only those dialysis facilities ''which meet such requirements as the Secretary shall by regulation prescribe for institutional dialysis services and supplies . . .'' also known as CfCs. The ESRD facility CfCs at 42 CFR part 494 are the minimum health and safety rules that all Medicare- and Medicaid-certified dialysis facilities must meet in order to participate in the programs. The ESRD CfCs were initially issued in 1976 and were comprehensively revised in 2008 (73 FR 20370). There are currently 7,893 Medicare-certified ESRD facilities in the U.S., serving over 500,000 patients.

Routine dialysis treatments, typically delivered 3 times per week, remove toxins from a patient's blood and are necessary to sustain life. Dialysis treatments are most often delivered in the ESRD facility but can be performed by the patients themselves at home, or in the patient's nursing facility with assistance. ESRD facilities serve patients whether they are diagnosed with COVID–19 or not, and people receiving dialysis cannot always be adequately distanced from one another during treatment. In-center dialysis precludes social distancing because it involves being in close proximity (<6 feet) to caregivers and fellow patients for extended periods of time (12–15 hours per week). Because dialysis patients are not able to defer dialysis sessions, in-center dialysis patients are at increased risk for developing COVID–19 due in part to difficulty maintaining physical distancing.[169] Many ESRD patients are also residents of LTC facilities or other congregate living settings, which is also a risk factor for COVID–19.[170] Further, individuals with kidney failure on dialysis may have a higher risk of worse outcomes.[171]

Dialysis health care personnel are considered a priority population for vaccination by the Advisory Committee on Immunization Practices (ACIP), yet ESRD facilities are currently reporting low COVID–19 vaccination coverage among ESRD facility health care personnel, at less than 63 percent as of September 26, 2021.[172] Ensuring health care personnel have access to COVID–19 vaccination is critical to protect both them and their medically fragile patients.[173]

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 494.30(b) related to establishing and implementing policies and procedures for COVID–19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

2. Community Mental Health Centers (CMHCs)

CMHCs are entities that meet applicable enrollment requirements, and applicable licensing or certification requirements in the State in which they are located. CMHCs provide the set of mental health care services specified in section 1913(c)(1) of the PHS Act (or, in limited circumstances, provides for such service by contract with an approved organization or entity). Section 4162 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, enacted November 5, 1990) (OBRA 1990), which added sections 1861(ff) and 1832(a)(2)(J) to the Act, includes CMHCs as entities that are authorized to provide partial hospitalization services under Part B of the Medicare program,

[168] *https://www.beckersasc.com/asc-news/5-ways-covid-19-affected-ascs-in-2020.html.* Accessed 10/17/2021.

[169] Am J Kidney Dis. 2020 Nov;76(5):690–695.e1. doi: 10.1053/j.ajkd.2020.07.001. Epub 2020 Jul 15.

[170] *https://www.jhunewsletter.com/article/2020/09/hopkins-finds-dialysis-patients-at-greater-risk-of-covid-19.*

[171] CJASN March 2021, 16 (3) 452–455; DOI: *https://doi.org/10.2215/CJN.12360720.*

[172] *http://www.synas.plus/nhsn/covid19/dial-vaccination-dashboard.html#anchor_1594393306.*

[173] *https://www.cdc.gov/vaccines/covid-19/planning/vaccinate-dialysis-patients-hcp.html,* accessed 09/08/2021 22:00 EDT.

effective for services provided on or after October 1, 1991. Section 1861(ff)(3)(B)(iv)(I) of the Act specifically requires CMHCs providing partial hospitalization services under Medicare to meet such additional conditions as the Secretary specifies to ensure the health and safety of individuals being furnished such services. Section 1866(e)(2) of the Act and 42 CFR 489.2(c)(2) recognize CMHCs as providers of services for purposes of provider agreement requirements but only with respect to providing partial hospitalization services. Pursuant to 42 CFR 410.2 and 410.110, a CMHC may receive Medicare payment for partial hospitalization services only if it demonstrates that it provides the core services identified in the requirements. To qualify for Medicare reimbursement, CMHCs must comply with requirements for coverage of partial hospitalization services at § 410.110 and conditions for Medicare payment of partial hospitalization services at 42 CFR 424.24(e).

Currently there are 129 Medicare-certified CMHCs in the U.S. The Secretary has established in regulations, at 42 CFR part 485, subpart J, the minimum health and safety standards a CMHC must meet to obtain Medicare certification. CMHC CoPs were issued on October 29, 2013 (78 FR 64604). Section 485.904, Personnel qualifications, establishes requirements for CMHC personnel. In this IFC we are adding new § 485.904(c) which requires the CMHC to meet the same COVID–19 vaccination of staff requirements as those we are issuing for the other providers and suppliers affected by this rule.

CMHCs provide mental health services to treat patients under the Medicare partial hospitalization program and other patients for various mental health conditions. Partial hospitalization programs provide structured, outpatient mental health services that are more intense than office visits with physicians or therapists. Patients in partial hospitalization programs receive treatment for several hours during the day, multiple days a week. In response to the PHE, CMHCs continued to treat patients by using telecommunications, and some centers paused their partial hospitalization programs or reduced the frequency and duration of treatment. However, many centers have begun to see and treat patients in person again and have resumed their customary partial hospitalization programming schedules. With increased in-person services being offered in the CMHC, it is essential to ensure all staff are vaccinated against COVID–19 not only to protect themselves but to prevent the spread of COVID–19 to CMHC patients.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 485.904(c) related to establishing and implementing policies and procedures for COVID–19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

3. Comprehensive Outpatient Rehabilitation Facilities (CORFs)

CORFs are non-residential facilities that are established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured persons, sick persons, and persons with disabilities, at a single fixed location, by or under the supervision of a physician. In response to the PHE, outpatient rehabilitation facilities suspended operations, reduced their patient care capacity, and transitioned from in-person to telecommunications as able. However, certain rehabilitation services require physical contact with patients, such as fitting or adjusting a prosthesis or assistive device and assessing strength with manual resistance. During the pandemic, some patients in need of rehabilitation chose to delay care and others encountered delays in accessing care. These delays likely contributed to increased disability or illness.[174] Moreover, patients admitted to the hospital have been discharged as soon as possible to provide beds for individuals with more critical conditions, including COVID–19. For those patients recovering from severe COVID–19 illness with long-term symptoms, prompt comprehensive outpatient rehabilitation services upon their discharge from inpatient care is necessary to restore physical and mental health.[175] All of these factors stress the importance of rehabilitation facilities who are treating patients with increased morbidity and complex needs. CORFs have resumed operations and are providing services to an increasing number of patients; therefore, COVID–19 vaccination of staff is pivotal for inhibiting spread of infection and ensuring health and safety of patients.

Currently, there are 159 Medicare-certified CORFs in the U.S. Section 1861(cc)(2)(J) of the Act states that the CORF must ''meet such conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such facility, including conditions concerning qualifications of personnel in these facilities.'' Under this authority, the Secretary has established in regulations, at 42 CFR part 485, subpart B, the minimum health and safety standards a CORF must meet to obtain Medicare certification. The CORF Conditions of Participation were issued on December 15, 1982 (47 FR 56282). Section 485.70, Personnel qualifications, sets forth the qualifications that various personnel must meet, as a condition of participation. We are adding a new paragraph (n) at § 485.70 which requires the CORF to meet the same COVID–19 vaccination of staff requirements as those we are issuing for the other providers and suppliers identified in this rule.

Our rules at § 485.58(d)(4), state that personnel that do not meet the qualifications specified in § 485.70 may be used by the facility in assisting qualified staff. We recognize this sentence is inconsistent with newly added § 485.70(n) which requires vaccination of all facility staff. We also recognize that assisting personnel are used by CORFs. We established our requirements at § 485.70 (a) through (m) to provide a role for personnel that might not meet our education and experience qualifications. We do not believe that this exception for employees that do not meet our professional requirements should prohibit us from issuing staff qualifications referencing infection prevention, which we intend to apply to all personnel. Hence, we are revising § 485.58(d)(4) to state that personnel that do not meet the qualifications specified in § 485.70(a) through (m) may be used by the facility in assisting qualified staff. However, such assisting staff will not be exempt from the newly added requirements in paragraph (n).

As with other parallel regulations for our facilities, we are revising § 485.58(d)(4) as previously discussed. For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 485.70(n) related to establishing and implementing policies and procedures for COVID–19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

[174] *https://gh.bmj.com/content/bmjgh/5/5/e002670.full.pdf.* Accessed 9/23/2021.

[175] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7027a2.htm?s_cid=mm7027a2_w* Accessed 9/23/2021.

4. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Section 1861(aa) and 1905(l)(2)(B) of the Act sets forth the RHC and FQHC services covered by the Medicare program; section 1905(l) cross-references the Medicare provision for Medicaid program purposes. The Act requires that RHCs be located in an area that is both rural and underserved, are not rehabilitation agencies or facilities primarily for the care and treatment of mental diseases, and meet such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are furnished services by the clinic. Likewise, 42 CFR 491.2 defines a FQHC as an entity as defined in § 405.2401(b). The definition at § 405.2401 includes an entity that has entered into an agreement with CMS to meet Medicare Program requirements under § 405.2434. And at 42 CFR 405.2434, the content and terms of the agreement require FQHCs to maintain compliance with requirements set forth in part 491, except the provisions of § 491.3 Certification procedures. Conditions for certification for RHCs and Conditions of Coverage for FQHCs are found at 42 CFR part 491, subpart A.

RHCs and FQHCs, as essential contributors to the health care infrastructure in the U.S., provide care and services to medically underserved areas and populations. They play a critical role in helping to alleviate access to care barriers and health equity gaps in these communities. RHCs and FQHCs provide primary care, diagnostic laboratory, and immunization services, and they have incorporated COVID–19 screening, triage, testing, diagnosis, treatment, and vaccination into these services. However, the medically underserved communities in the U.S. have been disproportionately affected by COVID–19. Hence, the Health Resources and Services Administration (HRSA) has established new programs to help RHCs and FQHCs meet the needs of their communities and ensure continuity of health care services during the PHE.[176] [177] [178] For example: (1) The Rural Health Clinic COVID–19 Testing and Mitigation Program which helps RHCs with COVID–19 testing and mitigation strategies to prevent the spread of infection; (2) the Rural Health Clinic Vaccine Distribution Program which strengthens COVID–19 vaccine allocations for RHCs; (3) the Rural Health Clinic Vaccine Confidence Program that helps RHCs with outreach efforts to improve vaccination rates in rural areas with nearly 2,000 RHCs across the nation participating; (4) the Health Center COVID–19 Vaccine Program whereby FQHCs receive direct allocations of vaccines; (5) the Department of Defense (DoD) and HHS partnered to provide point-of-care rapid COVID–19 testing supplies to FQHCs through the Health Center COVID–19 Testing Supply Distribution Program; and (6) delivery of 5.1 million adult and 7.4 million child masks between April and August 2021 to FQHCs at no cost for subsequent distribution to patients, staff, and community members. To implement these programs and to provide services and care, RHC/FQHC staff must interact with patients and members of the community at large. Hence, a requirement for these staff to receive COVID–19 vaccination is necessary to assure health and safety for the individuals residing in their respective service areas and their patients.

Currently, there are 4,933 Medicare- and Medicaid-certified RHCs and 10,384 FQHCs that participate in the Medicare and Medicaid programs in the U.S. The Conditions at 42 CFR part 491, subpart A are the minimum health and safety standards a center or clinic must meet to participate in the Medicare and Medicaid programs. The conditions were issued on June 12, 1992 (57 FR 27106), and the conditions related to staffing and staff responsibilities were last updated on May 12, 2014 (79 FR 27106). Section 491.8, Staffing and staff responsibilities, establishes requirements for RHC and FQHC staffing and staff responsibilities. We are adding new § 491.8(d) which requires the clinic or center to meet the same COVID–19 vaccination of staff requirements as those we are issuing for the other providers and suppliers identified in this rule.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 491.8(d) related to establishing and implementing policies and procedures for COVID–19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

5. Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

Under the authority of section 1861(p) of the Act, the Secretary has established CoPs that clinics, rehabilitation agencies, and public health agencies (collectively, ''organizations'') must meet when they provide outpatient physical therapy (OPT) and speech-language pathology (SLP) services. Under section 1861(p) of the Act, the Secretary is responsible for ensuring that the CoPs and their enforcement are adequate to protect the health and safety of individuals receiving OPT and SLP services from these entities. The CoPs are set forth at 42 CFR part 485, subpart H. Section 1861(p) of the Act describes outpatient physical therapy services to mean physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient. The patient must be under the care of a physician. The term ''outpatient physical therapy services'' also includes physical therapy services furnished to an individual by a physical therapist (in the physical therapist's office or the patient's home) who meets licensing and other standards prescribed by the Secretary in regulations, other than under arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency. Pursuant to the statutory requirement set out at section 1861(p)(4)(A) and (B) of the Act, the furnishing of such services by a clinic, rehabilitation agency, or public health agency must meet such conditions relating to health and safety as the Secretary may find necessary. The term also includes SLP services furnished by a provider of services, a clinic, rehabilitation agency, or by a public health agency, or by others under an arrangement.

Currently, there are 2,078 clinics, rehabilitation agencies, and public health agencies that provide outpatient physical therapy and speech-language services. In the remainder of this rule and throughout the requirements, we use the term ''organizations'' instead of ''clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services'' for consistency with current regulatory language. Patients receive services from organizations due to loss of functional

[176] *https://www.hrsa.gov/coronavirus/rural-health-clinics.* Accessed 9/24/2021.

[177] *https://bphc.hrsa.gov/emergency-response/coronavirus-frequently-asked-questions.* Accessed 9/24/2021.

[178] *https://www.hrsa.gov/coronavirus/health-center-program.* Accessed 10/6/2021.

ability associated with injury or illness. Hence, these patients experience episodic issues and seek care to restore their level of functioning and wellness to baseline. In response to the PHE, organizations experienced a reduction in patients. They supplemented in-person care with telecommunications. However, just over 50 percent of physical therapists report in-person care results in better outcomes than care provided virtually and the majority of patients are less satisfied with care received by telecommunications.[179] Although the data is limited, we believe these findings are consistent with other therapeutic services including occupational therapy and speech pathology. Comprehensive assessment of balance, strength, range-of-motion, and proper exercise technique is supported by physical touch, and three-dimensional visualization of the patient. Organizations have begun seeing more patients, and those patients are presenting with more severe functional issues. Organizations care for patients recovering from COVID–19 and those who delayed receiving non-COVID–19 related care due to fears of exposure to illness after the onset of the pandemic. These factors underscore the need to ensure safety and health of individuals who receive care from organizations with a requirement for COVID–19 vaccination of staff.

The CoPs for organizations at 42 CFR part 485, subpart H are the minimum health and safety standards an organization must meet to obtain Medicare certification. The CoPs were first issued May 21, 1976 (41 FR 20863), and the Conditions related to infection control were last updated on September 29, 1995 (60 FR 50446). Section 485.725, Infection control, requires organizations to establish an infection-control committee with responsibility for overall infection control. We are adding new paragraph (f) to § 485.725, which requires the organizations to meet the same COVID–19 vaccination of staff requirements as those we are issuing for the other providers and suppliers identified in this rule.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 485.725(f) related to establishing and implementing policies and procedures for COVID–19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

G. Home-Based Care

Home-based care providers provide necessary care and services for individuals who need ongoing therapeutic, and in some cases life-sustaining, care. These settings require that health care staff enter the patient's personal home (regardless of location in a private home, assisted living facility, or another setting) to provide services and care in person, thus exposing patients and other members of their household, to the staff. Home-based provider staff also often serve multiple patients in different homes in the same day, week, or month, which presents opportunities for transmission of infectious diseases across households. Because home-based providers work outside of a regulated health care facility, there is also the potential for staff to either not use the appropriate PPE or use it improperly because on-site oversight mechanisms are not in place, that could increase the risk of transmission of COVID–19 or other infectious diseases across households. We also believe these patients are especially vulnerable to COVID–19 due to receiving care in their homes. Many patients have serious illnesses that increases the risk of morbidity and mortality from COVID–19. For hospice patients that are receiving non-curative but supportive care, we are concerned that contracting COVID–19 could increase their discomfort, decrease their quality of life, or perhaps even hasten their death. In addition, the patients' homes may have poor ventilation or members of the household may not be complying with recommended safety precautions. Thus, COVID–19 vaccination mandates will provide patients and their household members with safety assurances that will facilitate acceptance of home care services, and will protect the patients, staff, and the other members of the patients' households.

1. Home Health Agencies (HHAs)

Under the authority of sections 1861(m), 1861(o), and 1891 of the Act, the Secretary has established in regulations the requirements that a home health agency (HHA) must meet to participate in the Medicare program, our regulations at 42 CFR 440.70(d) require that Medicaid-participating home health agencies meet Medicare conditions of participation. Section 1861(o)(6) of the Act requires that home health agencies ''meet the conditions of participation specified in section 1891(a) and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization.'' The CoPs for home health services are found in Title 42, Part 484, subparts A through C, §§ 484.40 through 484.115. HHAs provide care and services for qualifying older adults and people with disabilities who are beneficiaries under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program. These services include skilled nursing care, physical, occupational, and speech therapy, medical social work and home health aide services which must be furnished by, or under arrangement with, an HHA that participates in the Medicare program and must be provided in the beneficiary's home. As of September 1, 2021, there were 11,649 HHAs participating in the Medicare program. The majority of HHAs are for-profit, privately owned agencies. The effective delivery of quality home health services is essential to the care of the HHA's patients to provide necessary care and services and prevent hospitalizations. Since patients and other members of their households will be exposed to HHA staff, it is essential that staff be vaccinated against COVID–19 for the safety of the patients, members of their households, and the staff themselves.

With so many patients depending on the services of HHAs nationwide, it is imperative that HHAs have processes in place to address the safety of patients and staff and the continued provision of services. Because these patients are at home, essential care must be provided, regardless of COVID–19 vaccination or infection status. In addition, by going into patients' homes, HHA employees are exposed to numerous individuals who might not be vaccinated or perhaps are asymptomatic but infected. Therefore, it is imperative that HHAs have appropriate procedures to ensure the continued provision of care and services for their patients. Section 484.70 Condition of participation: Infection prevention and control (a) requires that the ''HHA must follow accepted standards of practice, including the use of standard precautions, to prevent the transmission of infections and communicable diseases.''

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 484.70(d) related to establishing and implementing policies and procedures for COVID–19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who

[179] American Physical Therapy Association. May 2021. Impact of COVID–19 on the Physical Therapy Profession Over One Year.

provide care, treatment, or other services for the provider or its patients.

2. Hospice

Section 122 of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97–248, enacted September 3. 1982) (TEFRA), added section 1861(dd) to the Act to provide coverage for hospice care to terminally ill Medicare beneficiaries who elect to receive care from a Medicare-participating hospice. Under the authority of section 1861(dd) of the Act, the Secretary has established the CoPs that a hospice must meet in order to participate in Medicare and Medicaid. Under section 1861(dd)(2)(G) of the Act, the Secretary may impose ''such requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization.'' The CoPs found at part 418, subparts C and D apply to a hospice, as well as to the services furnished to each patient under hospice care. These requirements are set forth in §§ 418.52 through 418.116.

Hospice care provides palliative care rather than curative treatment to terminally ill patients. Palliative care improves the quality of life of patients and their families and caregivers facing the challenges associated with terminal illness through the prevention and relief of suffering by means of early identification, assessment, and treatment of pain and other issues. Hospice care allows the patient to remain at home by providing support to the patient and family and caregiver and by keeping the patient as comfortable as possible while maintaining his or her dignity and quality of life. Hospices use an interdisciplinary approach to deliver medical, social, physical, emotional, and spiritual services through the use of a broad spectrum of support.

Hospices are unique health care providers because they serve patients, families, and caregivers in a wide variety of settings. Hospice patients may be served in their place of residence, whether that residence is a private home, an LTC facility, an assisted living facility, or even a recreational vehicle, as long as such locations are determined to be the patient's place of residence. Hospice patients may also be served in inpatient facilities, including those operated by the hospice itself.

With so many patients depending on the services of hospice services nationwide, it is imperative that hospices have processes in place to address the safety of patients and staff and the continued provision of services. The goal of hospice care is to provide non-curative, but supportive care of an individual during the final days, weeks, or months of a terminal illness. Contracting any infectious disease, especially COVID–19, could result in additional pain or perhaps even accelerate a patient's death. Thus, it is critical that hospices protect patients and staff from contracting or transmitting COVID–19. As of September 1, 2021, there were 5,556 hospices. Section 418.60(a), Condition of participation: Infection Control, requires that the ''hospice must follow accepted standards of practice to prevent the transmission of infections and communicable disease, including the use of standard precautions.''

The effective delivery of hospice services is essential to the care of the hospice's patients and their families and caregivers. Since patients and other members of their households will be exposed to hospice staff, it is essential that staff be vaccinated against COVID–19 for the safety of the patients, members of their households, and the staff themselves.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 418.60(d) related to establishing and implementing policies and procedures for COVID–19 vaccination of all staff (including employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

3. Home Infusion Therapy Suppliers (HIT) Suppliers

Section 5012 of the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016) (Cures Act) created a separate Medicare Part B benefit category under 1861(s)(2)(GG) of the Act for coverage of home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously or subcutaneously for periods of 15 minutes or more in the patient's home through a pump that is an item of durable medical equipment. Section 1861(iii)(3)(D)(i)(IV) of the Act requires qualified home infusion therapy (HIT) suppliers to meet, in addition to specified qualifications, ''such other requirements as the Secretary determines appropriate.'' The regulatory requirements for home therapy infusion (HIT) suppliers are located at 42 CFR part 486, subpart I, §§ 486.500 through 486.525.

The nature of the home setting presents different challenges than in-center services as well as the administration of the particular medications. The items and equipment needed to perform home infusion include the drug (for example, immune globulin), equipment (a pump), and supplies (for example, tubing and catheters) which are covered under the Durable Medical Equipment benefit. Skilled professional visits, such as those from nurses, often play a critical role in the provision of home infusion and are covered under the home infusion therapy benefit. For example, nurses typically train the patient or caregiver to self-administer the drug, educate on side effects and goals of therapy, and visit periodically to provide catheter and site care. Depending on patient acuity or the complexity of the drug administration, certain skilled professional visits may require more time. The HIT infusion process typically requires coordination among multiple entities, including patients, the responsible physicians and practitioners, hospital discharge planners, pharmacies, and, if applicable, home health agencies.

The current requirements for HIT suppliers do not contain specific infection prevention and control requirements. However, § 486.525, Required services, does state that these providers must ''provide home infusion therapy services in accordance with nationally recognized standards of practice, and in accordance with all applicable state and federal laws and regulations.'' We believe that ''nationally recognized standards of practice'' include appropriate policies and procedures for infection prevention and control.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 486.525(c) related to establishing and implementing policies and procedures for COVID–19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

4. Programs of All-Inclusive Care for the Elderly (PACE) Organizations

The Programs of All-Inclusive Care for the Elderly (PACE) program provides a model of managed care service delivery for frail older adults, most of whom are dually eligible for Medicare and Medicaid benefits, and all of whom are assessed as being eligible for LTC facility placement according to the Medicaid standards established by their respective states. PACE organizations furnish comprehensive medical, health, and social services that integrate acute and long-term care, and these services must be furnished in at least the PACE

center, the home, and inpatient facilities. The PACE model involves a multidisciplinary team of providers known as the interdisciplinary team (IDT) that comprehensively assesses and meets the needs of each PACE participant by planning and coordinating all participant care. PACE organizations must provide all Medicare-covered items and services, all Medicaid-covered items and services, and any other services determined necessary by the IDT to improve and maintain the participant's overall health status, either directly or under contract with third party service providers.

The statutory authorities that permit Medicare payments and coverage of benefits under the PACE program, as well as the establishment of PACE organizations as a State option under Medicaid to provide for Medicaid payments and coverage of benefits under the PACE program, are under sections 1894 and 1934 of the Act. These statutory authorities are implemented at 42 CFR part 460, where CMS has set out the minimum requirements an entity must meet to operate a PACE program under Medicare and Medicaid.

There are 141 PACE organizations nationally. These organizations serve approximately 52,000 participants, all in need of the comprehensive services provided by PACE organizations. Due to their health status, PACE participants are at high risk of severe COVID–19 and as such have been among the populations prioritized for vaccination since the vaccines were authorized. Participants' regular interactions with PACE organization staff and contractors indicate that those staff and contractors should also be vaccinated against COVID–19.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding new regulatory requirements at § 460.74(d) related to establishing and implementing policies and procedures for COVID–19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services on behalf of a PACE organization.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule before the provisions of the rule take effect, in accordance with the Administrative Procedure Act (APA), 5 U.S.C. 553, and section 1871 of the Act. Specifically, section 553(b) of the APA requires the agency to publish a notice of the proposed rule in the **Federal Register** that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. Section 553(c) further requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and a period of not less than 60 days for public comment. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize the agency to waive these procedures, however, if the agency finds good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

The 2021 outbreaks associated with the SARS–Cov–2 Delta variant have shown that current levels of COVID–19 vaccination coverage up until now have been inadequate to protect health care consumers and staff. The data showing the vital importance of vaccination indicate to us that we cannot delay taking this action in order to protect the health and safety of millions of people receiving critical health care services, the workers providing care, and our fellow citizens living and working in communities across the nation.

Although section 564 of the FDCA does not prohibit public or private entities from imposing vaccination requirements, even when the only vaccines available are those authorized under EUAs (*https://www.justice.gov/olc/file/1415446/download*), CMS initially chose, among other actions, to encourage rather than mandate vaccination, believing that a combination of other Federal actions, a variety of public education campaigns, and State and employer-based efforts would be adequate. However, despite all of these efforts, including CMS's mandate for vaccination education and offering of vaccines to LTC facility and ICF–IID staff, residents, and clients (86 FR 26306), OSHA's June 21, 2021 ETS to protect health care and health care support service workers from occupational exposure to COVID–19 (86 FR 3276), and ongoing CDC information and encouragement, vaccine uptake among health care staff has not been as robust as hoped for and have been insufficient to protect the health and safety of individuals receiving health care services from Medicare- and Medicaid-certified providers and suppliers, particularly given the advent of the Delta variant and the potential for new variants.

As discussed throughout the preamble of this IFC, the PHE continues to strain the U.S. health care system. Over the first 6 months of 2021, COVID–19 cases, hospitalizations and deaths declined. The emergence of the Delta variant reversed these trends.[180] Between late June 2021 and September 2021, daily cases of COVID–19 increased over 1200 percent; new hospital admissions, over 600 percent; and daily deaths, by nearly 800 percent.[181] Available data also continue to suggest that the majority of COVID–19 cases and hospitalizations are occurring among individuals who are not fully vaccinated. From January through May 2021, of the more than 32,000 laboratory-confirmed COVID–19-associated hospitalizations in adults over 18 years of age for whom vaccination status is known, less than 3 percent of hospitalizations occurred in fully vaccinated persons.[182] More recently published data continue to suggest that fully vaccinated persons account for a minority (~10 percent) of COVID–19 related hospitalizations.[183] For all adults aged 18 years and older, the cumulative COVID–19-associated hospitalization rate was about 12-times higher in unvaccinated persons.[184] Consequently, some hospitals and health care systems are currently experiencing tremendous strain due to high case volume coupled with persistent staffing shortages due, at least in part, to COVID–19 infection or quarantine following exposure.

We recognize that newly reported COVID–19 cases, hospitalizations, and deaths have begun to trend downward at a national level; nonetheless, they remain substantially elevated relative to numbers seen in May and June 2021, when the Delta variant became the predominant strain circulating in the U.S.[185] And while cases are trending

[180] *https://emergency.cdc.gov/han/2021/han00447.asp.*

[181] Internal estimates based on data published at *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html;* accessed September 24, 2021.

[182] *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html,* accessed October 18, 2021.

[183] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm?s_cid=mm7037e1_w,* accessed October 18, 2021.

[184] *https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination,* accessed October 18, 2021.

[185] *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

downward in some states, there are emerging indications of potential increases in others—particularly northern states where the weather has begun to turn colder. This is not surprising: Respiratory virus infections typically circulate more frequently during the winter months, with peaks in pneumonia and influenza deaths typically during winter months.[186] Similarly, the U.S. experienced a large COVID–19 wave in the winter of 2020. Approximately 1 in 3 people 12 years of age and older in the U.S. remain unvaccinated—and they could pose a threat to the country's progress on the COVID–19 pandemic, potentially incurring a fifth wave of COVID–19 infections.[187]

The onset of the 2021–2022 influenza season presents an additional threat to patient health and safety. Although influenza activity during the 2020–2021 season was low throughout the U.S.,[188] the intensity of the upcoming 2021–2022 influenza season cannot be predicted. Several factors could make this flu season more severe; these include return to school by children with no prior exposure to flu (and therefor lower immunity), waning protection over time from previous seasonal influenza vaccination, and the fact that adult immunity (especially among those who were not vaccinated last season) will now partly depend on exposure to viruses two or more seasons earlier.[189] [190] COVID–19 vaccination thus remains an important tool for decreasing stress on the U.S. health care system during ongoing circulation of influenza. As previously noted, health system strain can adversely impact patient access to care and care quality.

Furthermore, data on the health consequences of coinfection with influenza and SARS–CoV–2 are limited. Preliminary evidence suggests that a combination of infections with influenza and SARS–CoV–2 would result in more severe health outcomes for patients than either infection alone.[191] [192] [193] However, COVID–19 is more infectious and has greater rates of mortality, hospitalizations, and severe illness than influenza. Accordingly, it is imperative that the risk for healthcare-associated COVID–19 transmission be minimized during the influenza season. Influenza is most common during the fall and winter with the highest incidence of cases reported between December through March.[194] COVID–19 vaccines require time after administration for the body to build an immune response. Hence, given that the influenza season is imminent, a staff COVID–19 vaccination requirement for the providers and suppliers identified in this rule cannot be further delayed. The impact of unvaccinated populations on the health-care system and the inconsistent web of State, local, and employer COVID–19 vaccination requirements have established a pressing need for a consistent Federal policy mandating staff vaccination in health care settings that receive Medicare and Medicaid funds. The current patchwork of regulations undermines the efficacy of COVID–19 vaccine mandates by encouraging unvaccinated workers to seek employment at providers that do not have such patient protections, exacerbating staffing shortages, and creating disparities in care across populations. This includes workers moving between various types of providers, such as from LTC facilities to HHAs and others, creating imbalances. As discussed in section I. of this IFC, we have received numerous requests from diverse stakeholders for Federal intervention to implement a health-care staff vaccine mandate.[195] Of particular note, several representatives of the long-term care community (not limited to Medicare- and Medicaid-certified LTC facilities) expressed concerns about inequities that would result from imposition of a mandate on only one type of provider and strongly recommended a broad approach.[196] While there is opposition to the vaccine mandate, a combination of factors now have persuaded us that a vaccine mandate for health care workers is an essential component of the nation's COVID–19 response, the delay of which would contribute to additional negative health outcomes for patients including loss of life. These include, but are not limited to, the following: Failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements; ongoing risk of new COVID–19 variants; potential harmful impact of unvaccinated healthcare workers on patients; continuing strain on the health care system, particularly from Delta-variant-driven surging case counts beginning in summer 2021; demonstrated efficacy, safety and real-world effectiveness of available vaccines; FDA's full licensure of the Pfizer-BioNTech's Comirnaty vaccine; our observations of the efficacy of COVID–19 vaccine mandates in other settings; and the calls from numerous stakeholders for Federal intervention. Moreover, a further delay in imposing a vaccine mandate would endanger the health and safety of additional patients and be contrary to the public interest.

We note that health care workers were among the first groups provided access to vaccinations, which were initially authorized for emergency use. EUA status may have been a factor in some individual decisions to delay or refuse vaccination. The Pfizer-BioNTech COVID–19 vaccine was first authorized for emergency use on December 11, 2020. The vaccine continues to be available in the U.S. under EUA, and the EUA was subsequently amended to include use in individuals 12 through 15 years of age, to allow for the use of an additional dose in the primary series for certain immunocompromised individuals, and to allow for use of a single booster dose to be administered at least 6 months after completion of the primary series in certain individuals. FDA has issued EUAs for two additional vaccines for the prevention of COVID–19, one to Moderna (December 18, 2020) (indicated for use by individuals 18 years of age and older), and the other to Janssen (Johnson & Johnson) (February 27, 2021) (indicated for use by individuals 18 years of age and older). Fact sheets for health care providers administering vaccine are available for each vaccine product from FDA. However, on August 23, 2021, FDA licensed Pfizer-BioNTech's Comirnaty Vaccine. Health care workers whose hesitancy was related to EUA status now have a fully licensed COVID–19 vaccine option. Despite this, as noted earlier, health care staff vaccination rates remain sub-optimal in too many health care facilities and regions. For example, national COVID–19 vaccination rates for LTC facility, hospital, and ESRD facility staff are 67 percent, 64 percent, and 60 percent, respectively. Moreover, these averages obscure sizeable regional differences.

[186] *https://www.cdc.gov/flu/professionals/acip/background-epidemiology.htm.*

[187] Ibid.

[188] CDC. FluView. Weekly influenza surveillance report. Atlanta, GA: U.S. Department of Health and Human Services, CDC. Accessed February 11, 2021. *https://www.cdc.gov/flu/weekly/index.htm.*

[189] *https://www.medrxiv.org/content/10.1101/2021.08.29.21262803v1.*

[190] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7029a1.htm.*

[191] *https://academic.oup.com/cid/article/72/12/e993/6024509?login=true.*

[192] *https://onlinelibrary.wiley.com/doi/epdf/10.1002/jmv.26163.*

[193] *https://www.cdc.gov/flu/about/season/flu-season.htm.*

[194] Ibid.

[195] *https://www.aamc.org/news-insights/press-releases/major-health-care-professional-organizations-call-covid-19-vaccine-mandates-all-health-workers.* Accessed 10/06/2021.

[196] *https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-september-2021/.* Accessed 10/06/2021.

LTC facility staff vaccination rates range from lows of 56 percent to highs of over 90 percent, depending upon the State. Similar patterns hold for ESRD facility and hospital staff.[197] [198] [199]

Over half a million COVID–19 cases and 1,900 deaths among health care staff have been reported to CDC since the start of the PHE.[200] When submitting case-level COVID–19 reports, State and territorial jurisdictions may identify whether individuals are or are not health care workers. Since health care worker status has only been reported for a minority of cases (approximately 18 percent), these numbers are likely gross underestimates of true burden in this population. COVID–19 case rates among staff have also grown in tandem with broader national incidence trends since the Delta variant's emergence. For example, as of mid-September 2021, COVID–19 cases among LTC facility and ESRD facility staff have increased by over 1400 percent and 850 percent, respectively, since their lows in June 2021.[201] Similarly, the number of cases among staff for whom case-level data were reported by State and territorial jurisdictions to CDC increased by nearly 600 percent between June and August 2021.[202] Because they are at greater risk for developing COVID–19 infection and severe disease,[203] [204] [205] unvaccinated staff present a risk of exacerbating ongoing staffing shortages—particularly during periods of community surges in SARS–CoV–2 infection, when demand for health care services is most acute. Health care staff who remain unvaccinated may also pose a direct threat to patient, resident, workplace, family, and community safety and population health. Data from CDC's National Healthcare Safety Network (NHSN) have shown that case rates among LTC facility residents are higher in facilities with lower vaccination coverage among staff; specifically, residents of LTC facilities in which vaccination coverage of staff is 75 percent or lower experience higher crude rates of preventable SARS–CoV–2 infection.[206] Similarly, several articles published in CDC's Morbidity and Mortality Weekly Reports (MMWRs) regarding nursing home outbreaks have also linked the spread of COVID–19 infection to unvaccinated health care workers and stressed that maintaining a high vaccination rate is important for reducing transmission.[207] [208] [209] And multiple studies have demonstrated SARS–CoV–2 transmissions between health-care workers and patients in hospitals, despite universal masking and other protocols.[210] [211] [212] [213] Acute and LTC facilities engage many, if not all, of the same health care professionals and support services of other provider and supplier types. As a result, while similarly comprehensive data are not available for all Medicare- and Medicaid-certified provider and supplier types, we believe the LTC facilities experience may generally be extrapolated to other settings.

The efficacy of COVID–19 vaccinations has been demonstrated.[214] An ASPE report published on October 5, 2021, found that COVID–19 vaccines are a key component in controlling the COVID–19 pandemic. Clinical data show vaccines are highly effective in preventing COVID–19 cases and severe outcomes including hospitalization and death. The ASPE analysis of individual-level health data and county-level vaccination rates found that higher county vaccination rates were associated with significant reductions in the odds of COVID–19 infection, hospitalization, and death among Medicare fee-for-service (FFS) beneficiaries between January and May 2021. Further, comparing the rates of these outcomes to what ASPE modeling predicted would have happened without any vaccinations, we estimate COVID–19 vaccinations were linked to estimated reductions of approximately 107,000 infections, 43,000 hospitalizations, and 16,000 deaths in our study sample of 25.3 million beneficiaries. The report also noted that the difference in vaccination rates for those age 65 and older between the lowest (34 percent) and highest (85 percent) counties and states by the end of May highlights the continued opportunity to leverage COVID–19 vaccinations to prevent COVID–19 hospitalizations and deaths.[215] Vaccines continue to be effective in preventing COVID–19 associated with the now-dominant Delta variant.[216] [217]

In addition to preventing morbidity and mortality associated with COVID–19, the vaccines also appear to be effective against asymptomatic SARS–CoV–2 infection. A recent study of health care workers in 8 states found that, between December 14, 2020, through August 14, 2021, full vaccination with COVID–19 vaccines was 80 percent effective in preventing RT–PCR–confirmed SARS–CoV–2 infection among frontline workers.[218] Emerging evidence also suggests that vaccinated people who become infected with Delta have potential to be less infectious than infected unvaccinated people, thus decreasing transmission risk.[219] For example, in a study of breakthrough infections among health care workers in the Netherlands, SARS–CoV–2 infectious virus shedding was lower among vaccinated individuals with breakthrough infections than

[197] LTC facility rates derived from data reported through CDC's NHSN and posted online at the Nursing Home COVID–19 Vaccination Data Dashboard: *https://www.cdc.gov/nhsn/covid19/ltc-vaccination-dashboard.html;* accessed September 15, 2021.

[198] Dialysis facility rates derived from data reported through CDC's NHSN and posted online at the Dialysis COVID–19 Vaccination Data Dashboard: *https://www.cdc.gov/nhsn/covid19/dial-vaccination-dashboard.html;* accessed September 15, 2021.

[199] Hospital data come from unpublished analyses of data reported to HHS and posted on HHS Protect.

[200] *https://covid.cdc.gov/covid-data-tracker/#health-care-personnel;* accessed September 24, 2021.

[201] Analysis of dialysis facility and nursing home data reported through NHSN.

[202] Ibid. 110.

[203] *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html.*

[204] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm?s_cid=mm7037e1_w.*

[205] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm?s_cid=mm7034e4_w.*

[206] *https://emergency.cdc.gov/han/2021/han00447.asp.*

[207] COVID–19 Outbreak Associated with a SARS–CoV–2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program—Kentucky, March 2021.'' April 21, 2021. Available at *https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e2.htm.*

[208] Postvaccination SARS–CoV–2 Infections Among Skilled Nursing Facility Residents and Staff Members—Chicago, Illinois, December 2020–March 2021.'' April 30, 2021. Available at *https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e1.htm.*

[209] Effectiveness of the Pfizer-BioNTech COVID–19 Vaccine Among Residents of Two Skilled Nursing Facilities Experiencing COVID–19 Outbreaks—Connecticut, December 2020–February 2021.'' March 19, 2021. Available at *https://www.cdc.gov/mmwr/volumes/70/wr/mm7011e3.htm.*

[210] Klompas M, Baker MA, Griesbach D, et al. Transmission of SARS–CoV–2 from asymptomatic and presymptomatic individuals in healthcare settings despite medical masks and eye protection. Clin Infect Dis. 2021. [PMID: 33704451] doi:10.1093/cid/ciab218.

[211] *https://www.medrxiv.org/content/10.1101/2021.02.16.21251625v1.*

[212] *https://jamanetwork.com/journals/jama/fullarticle/2773128.*

[213] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8349432/.*

[214] *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html.*

[215] *https://aspe.hhs.gov/sites/default/files/documents/c5d0dde224c224dd726694367846b609/aspe-covid-medicare-vaccine-analysis.pdf.* Accessed 10/06/2021.

[216] *https://www.nejm.org/doi/full/10.1056/nejmoa2108891.*

[217] *https://www.mayoclinic.org/coronavirus-covid-19/covid-variant-vaccine.*

[218] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm?s_cid=mm7034e4_w.*

[219] *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html#ref43.*

among unvaccinated individuals with primary infections.[220]

As noted earlier in this section, a combination of factors, including but not limited to failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements, potential harm to patients from unvaccinated health-care workers, and continuing strain on the health care system and known efficacy and safety of available vaccines, have persuaded us that a vaccine mandate for health care workers is an essential component of the nation's COVID–19 response. Further, it would endanger the health and safety of patients, and be contrary to the public interest to delay imposing it. Therefore, we believe it would be impracticable and contrary to the public interest for us to undertake normal notice and comment procedures and to thereby delay the effective date of this IFC. We find good cause to waive notice of proposed rulemaking under the APA, 5 U.S.C. 553(b)(B), and section 1871(b)(2)(C) of the Act. For those same reasons, as authorized by the Small Business Regulatory Enforcement Fairness Act of 1996 (the Congressional Review Act or CRA), 5 U.S.C. 808(2), we find it is impracticable and contrary to the public interest not to waive the delay in effective date of this IFC under section 801 of the CRA. Therefore, we find there is good cause to waive the CRA's delay in effective date pursuant to section 808(2) of the CRA.

[220] *https://www.medrxiv.org/content/10.1101/2021.08.20.21262158v1.full.pdf.*

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement (ICR) is submitted to the Office of Management and Budget (OMB) for review and approval. The ICRs in this section will be included in an emergency revision of the information collection request currently approved under the appropriate OMB Control number. All PRA-related comments received in response to this IFC will be reviewed and addressed in a subsequent, non-emergency, submission of the information collection request. The emergency approval is only valid for 6 months. Within that 6-month approval period, CMS will seek a regular, non-emergency, approval and as required by the PRA, this action will be announced in the requisite 60-day and 30-day **Federal Register** notices.

In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

For the estimated costs contained in the analysis below, we used data from the U.S. Bureau of Labor Statistics (BLS) to determine the mean hourly wage for the positions used in this analysis.[221] For the total hourly cost, we doubled the mean hourly wage for a 100 percent increase to cover overhead and fringe benefits, according to standard HHS estimating procedures. If the total cost after doubling resulted in 0.50 or more, the cost was rounded up to the next dollar. If it was 0.49 or below, the total cost was rounded down to the next dollar. The total costs used in this analysis are indicated in Table 3.

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[221] BLS. *May 2020 National Occupational Employment and Wage Estimates United* States. United States Department of Labor. Accessed at *https://www.bls.gov/oes/current/oes_nat.htm.* Accessed on August 25, 2021.

TABLE 3: Summary Information of Estimated Mean Hourly and Adjusted Hourly Wages

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
29-1228	Physicians, All Others; and Ophthalmologist, except Pediatric) (General Medical and Surgical Hospitals)	LTC Facility Medical Director	$85.70	$171
29-1141	Registered Nurses (Nursing Facilities/ Skilled Nursing Facilities)	LTC Facility Registered Nurse (RN): LTC Facility Infection Preventionist (IP); ICFs-IID RN	$34.66	$69
29-1141	Registered Nurses (Home Health Care Services)	HHA RN; RN HIT; ESRD RN	$36.48	$73
29-1141	Registered Nurses (General Medical and Surgical Hospitals)	RN Hospice; RN Hospital; RN CAH	$39.27	$79
29-1141	Registered Nurses (Psychiatric and Substance Abuse Hospitals)	RN PRTF	$37.14	$74
11-9111	Medical and Health Services Managers (Nursing Facilities/Skilled Nursing Facilities)	LTC Facility Director of Nursing (DON); ICFs-IID Administrator	$48.15	$96
11-9111	Medical and Health Services Managers (General Medical and Surgical Hospitals)	Hospice Administrator; Hospital Administrator; Hospital DON; CAH DON; CAH Administrator; PRTF Administrator	$61.22	$122
11-9111	Medical and Health Services Managers (Home Health Care Services)	HHA Administrator; HIT Administrator; ESRD Administrator	$48.50	$97
29-1215	Family Medicine Physicians (Ambulatory Health Care Services, Offices of Physicians)	Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) Physician and Medical Director	$105.75	$212

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
29-1071	Physician Assistants (Ambulatory Health Care Services, Offices of Physicians)	Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) Physician Assistant	$55.34	$111
29-1171	Nurse Practitioners (Ambulatory Health Care Services, Offices of Physicians)	Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) Nurse Practitioner	$53.51	$107
29-1123	Physical Therapists (Ambulatory Health Care Services, Offices of Other Health Practitioners)	Physical Therapist	$41.91	$84
29-1141	Registered Nurses (national mean hourly wage)	Ambulatory Surgery Center (ASC) Infection Control Professional (ICP)	$38.47	$77
11-9111	Medical and Health Services Managers (Ambulatory Health Care Services, Offices of Physicians)	Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) Administrator	$54.18	$108
11-9111	Medical and Health Services Managers (Ambulatory Health Care Services, Outpatient Care Centers)	Community Mental Health Center (CHMC) Administrator	$56.34	$113
11-9111	Medical and Health Services Managers (Ambulatory Health Care Services, Other Ambulatory Health Care Services)	Ambulatory Surgery Center (ASC) Administrator, Organization Administrator, and Comprehensive Outpatient Rehabilitation Facility (CORF) Administrator	$49.03	$98
29-9092	General Counselors (Ambulatory Health Care Services, Outpatient Care Centers)	Community Mental Health Center (CHMC) Mental Health Counselor	$59.17	$118

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In this analysis, we used specific resources to estimate the burden for the providers and suppliers in this rule. Based upon our experience, there are minimal fluctuations in the numbers of providers and suppliers monthly. Thus, unless otherwise indicated, all of the numbers for the providers and suppliers in this analysis were located on September 1, 2021 on the Quality, Certification & Oversight Reports (QCOR) website at *https://qcor.cms.gov/main.jsp.* For the number of employees for each provider and supplier, those numbers were obtained from Table 5: Estimates of Number of Staff by Type of Provider (thousands) located in section VI.B. of this IFC.

This analysis is also based upon certain assumptions. We believe that many of the providers and suppliers covered in this rule have already either encouraged their employees to get

vaccinated for COVID–19 or have mandates for the vaccine. Mandates for employees to be vaccinated for COVID–19 can result from State, county, or local actions or result from a decision by the facility. These facilities would likely have already developed policies and procedures, as well as documentation requirements, related to their employees being vaccinated for COVID–19. However, we have no reliable method to estimate the number or percentage of these facilities. In addition, it is likely that those facilities would not comply with all of the requirements in this rule. For example, many facilities might not define ''employees'' as set forth in this rule. Each facility would have to review its policies, procedures, and documentation requirements to ensure that they comply with the requirements in this rule. Hence, based upon these assumptions, this analysis will assess the burden for all facilities and employees for each provider and supplier type.

We also made some assumption regarding analysis of the burden for the documentation requirements. If an employee receives the appropriate vaccinations, reviewing and documenting that the employee has been vaccinated would likely only require 1 to 3 minutes, depending upon how the facility is documenting the vaccination, which is likely to vary substantially between facilities. However, for employees that request exemptions or have to be contacted repeatedly for the appropriate documentation, it would likely take more time to comply with this requirement. At a minimum, both the initial request for the exemption and the final determination would have to be documented. In cases where the exemption was denied and the employee receives the appropriate vaccinations, those vaccine doses would also have to be documented. There might also be additional documentation that would need to be copied or scanned for their records. While the documentation for employees requesting an exemption would require more burden, we believe that there would only be a small percentage of employees that would request an exemption. Since we have no reliable method for estimating a number or percentage of employees who would be in each category, we will analyze the burden for the documentation requirements using 5 minutes or 0.0833 hours for each employee.

The position of the individual who would perform the activities related to the documentation requirement would also vary depending upon the type of provider or supplier and whether the employee requested an exemption. If the employee has been vaccinated in compliance with this rule, an administrative support person might review their vaccination card and document that the employee has been vaccinated. However, if an administrative support person performs these activities, we believe an administrator or another member of the health care staff would be responsible for overseeing these activities. For other providers and suppliers, a nurse would likely be assigned to verify and document vaccination status. If an employee requests an exemption, we believe that a nurse, another health care professional, or an administrator would likely review the request and document it. Some other providers or suppliers might have an administrator or another member of the health care staff perform these activities. Thus, for this analysis, if a provider is required to have at least one infection preventionist (IP), such as hospitals, we believe the IP would be responsible for documenting the vaccination status for all employees. For other providers and suppliers, we assessed the burden using a registered nurse (RN), another member of the health care staff, such as a physical therapist, or an administrator.

The estimates that follow are largely based on our experience with these various providers. However, given the uncertainty and rapidly changing nature of the current pandemic, we acknowledge that there will likely need to be revisions to these requirements over time. We welcome comments that might improve these estimates.

A. ICRs Regarding the of Development of Policies and Procedures for ASCs § 416.51(c), ''COVID–19 Vaccination of Staff''

1. Policies and Procedures

At § 416.51(c), we require ASCs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID–19 and track and maintain documentation of their vaccination status. Each ASC must also have a contingency plan for any staff that are not fully vaccinated according to this rule.

The ICRs for this section would require each ASC to develop the policies and procedures needed to satisfy all of the requirements in this section. Based upon our experience with ASCs, we believe some centers have already developed policies and procedures requiring COVID–19 vaccination for staff. However, each ASC will need to review their current policies and procedures and modify them, if necessary, to ensure compliance with the requirements in this IFC, especially that their policies and procedures cover all of the center staff as identified in this IFC. Hence, we will base our estimate for this ICR on all 6,071 ASCs. We believe activities associated with this IFC would be performed by the RN functioning as the designated and qualified infection control professional (ICP) and ASC administrator as analyzed below.

The ICP would conduct research and then either modify or develop the policies and procedures needed to comply with this section's requirements. The ICP would work with the ASC administrator in developing these policies and procedures. For the ICP, we estimate this would require 8 hours initially to perform research and revise or develop the policies and procedures to meet these requirements. According to Table 3, the ICP's total hourly cost is $77. Thus, for each ASC, the burden for the ICP would be 8 hours at a cost of $616 ($8 \times \$77$). For the ICPs in all 6,071 ASCs, the burden would be 48,568 hours ($8 \times 6{,}071$) at an estimated cost of $3,739,736 ($\$616 \times 6{,}071$).

As discussed above, the revision and approval of these initial policies and procedures would also require activities by the ASC administrator. The administrator would need to have meetings with the ICP to discuss the revisions and approve the final policies and procedures. We estimate this would require 2 hours for the administrator. According to Table 3, the total hourly cost for the administrator is $98. The burden for the administrator in each ASC would be 2 hours at an estimated cost of $196 ($2 \times \$98$). For the administrators in all 6,071 ASCs, the burden would be 12,142 hours ($2 \times 6{,}071$) at an estimated cost of $1,189,916 ($\$196 \times 6{,}071$).

Therefore, for all 6,071 ASCs, the estimated burden associated with the requirement for policies and procedures would be 67,010 hours (48,568 + 12,142) at a cost of $4,929,652 ($3,739,736 + $1,189,916).

2. Documentation and Storage

Section 416.51(c) also requires ASCs to track and securely maintain the required documentation of staff COVID–19 vaccination status. Any burden for modifying the center's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation an adjusted hourly wage of $77 for each employee. According to Table 3, ASCs have 200,000 employees.

Hence, the burden for these documentation requirements for all 6,071 ASCs would be 16,660 (0.0833 × 200,000) hours at an estimated cost of $1,282,820 (16,660 × $77).

The total burden for all 6,071 ASCs for this IFC would be 83,670 (67,010 + 16,660) hours at an estimated cost of $6,212,472 ($4,929,652 + $1,282,820).

The requirements and burden will be submitted to OMB under OMB control number 0938–0266 (expiration date July 31, 2024).

B. ICRs Regarding the Development of Policies and Procedures for Hospices § 418.60(d), ''COVID–19 Vaccination of Facility Staff''

1. Policies and Procedures

At § 418.60(d), we require hospices to develop and implement policies and procedures to ensure their staff are vaccinated for COVID–19 and that appropriate documentation of those vaccinations are tracked and maintained. The hospice must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each hospice to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations are set forth at § 418.60 Condition of participation: Infection control, and require each hospice to maintain and document an infection control program to prevent and control infections and communicable diseases. The hospice must also follow accepted standards of practice, including the use of standard precautions to prevent the transmission of infections and communicable diseases. Thus, all hospices should already have infection prevention and control policies and procedures, but they likely do not comply with all of the requirements in this IFC.

All hospices would need to review their current policies and procedures and modify them to comply with all of the requirements in § 418.60(d) as set forth in this IFC. While we believe that many hospices have already addressed COVID–19 vaccination with their staff, we have no reliable means to estimate that number. Therefore, we will assess the burden for these requirements for all 5,556 hospices. We believe these activities would be performed by the RN and an administrator. According to Table 3, an RN in these settings has a total hourly cost of $79. Since there are not any current requirements that address COVID–19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each hospice, the burden for the RN would be 8 hours at a cost of $632 (8 hours × $79). For all 5,556 hospices, the burden would be 44,448 hours (8 hours × 5,556) at an estimated cost of $3,511,392 ($632 × 5,556).

As discussed above, the revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 3, the total hourly cost for the administrator in this setting is $122. Hence, for each hospice, the burden would be 2 hours at an estimated cost of $244 (2 × $122). For all 5,556 hospices, the total burden would be 11,112 hours (2 × 5,556) at an estimated cost of $1,355,664 (5,556 × $244).

Thus, the total burden for hospices to comply with the requirements for policies and procedures in this IFC is 55,560 hours (44,448 + 11,112) at an estimated cost of $4,867,056 ($3,511,392 + $1,355,664).

2. Documentation and Storage

Section 418.60(d) also requires hospices to track and securely maintain the required documentation of staff COVID–19 vaccination status. Any burden for modifying the hospice's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation an adjusted hourly wage of $79 for each employee. According to Table 3, hospices have 340,000 employees. Hence, the burden for these documentation requirements for all 5,556 hospices would be 28,322 (0.0833 × 340,000) hours at an estimated cost of $2,237,438 (28,322 × 79).

Therefore, the total burden for all 5,556 hospices for this rule would be 83,882 (55,560 + 28,322) hours at an estimated cost of $7,104,494 (4,867,056 + 2,237,438).

The requirements and burden will be submitted to OMB under OMB control number 0938–1067 (expiration date March 31, 2024).

C. ICRs Regarding the Development of Policies and Procedures for PACE Organizations § 460.74(d), ''COVID–19 Vaccination of PACE Organization Staff''

1. Policies and Procedures

Section 460.74(d) requires that programs for all-inclusive care for the elderly (PACE) organizations to develop and implement policies and procedures to ensure their staff are vaccinated for COVID–19 and that appropriate documentation of those vaccinations are tracked and maintained. Each PACE organization must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each PACE organization to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 460.74 already require that each PACE organization follow accepted policies and standard procedures with respect to infection control in place. Thus, all PACE organizations should have policies and procedures regarding infection prevention and control. We also believe that many have already addressed COVID–19 vaccination policies for their staff. However, since we do not have a reliable method to estimate how many have, we will assess the burden for all 141 PACE organizations.

All PACE organizations would need to review their current infection prevention and control policies and procedures and develop or modify them to satisfy the requirements in this section. We believe these activities would require an RN and an administrator. According to Table 3, an RN's total hourly cost is $74. Since there are not any current requirements that address COVID–19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each PACE organization, the burden for the RN would be 8 hours at a cost of $592 (8 hours × $74). For all 141 PACE organizations, the burden would be 1,128 hours (8 hours × 141) at an estimated cost of $83,472 (592 × 141).

As discussed above, the revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 3, the total hourly cost for the administrator is $122. Hence, for each PACE organization, the burden would be 2 hours at an estimated cost of $244 (2 × 122). For all 141 PACE organizations, the total burden would be 282 hours (2 × 141) at an estimated cost of $34,404 (141 × $244).

Thus, the total burden for all 141 PACE organizations to comply with the requirements for the policies and

procedures is 1,410 hours (1,128 + 282) at an estimated cost of $117,876 (83,472 + 34,404).

2. Documentation and Storage

Section 460.74(d) also requires PACE organizations to track and securely maintain the required documentation of staff COVID–19 vaccination status. Any burden for modifying the PACE organization's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation an adjusted hourly wage of $74 for each employee. According to Table 3, PACE organizations have 10,000 employees. Hence, the burden for these documentation requirements for all 141 PACE organizations would be 833 (0.0833 × 10,000) hours at an estimated cost of $61,642 (833 × 74).

Therefore, the total burden for all 141 PACE organizations for this rule would be 2,243 (1,410 + 833) hours at an estimated cost of $179,518 (117,876 + 61,642).

The requirements and burden will be submitted to OMB under OMB control number 0938–1326 (expiration date April 20, 2023).

D. ICRs Regarding the Development of Policies and Procedures for Hospitals § 482.42(g), ''COVID–19 Vaccination of Hospital Staff''

1. Policies and Procedures

At § 482.42(g), we require hospitals to develop and implement policies and procedures to ensure their staff are vaccinated for COVID–19 and that appropriate documentation of those vaccinations are tracked and maintained. The hospital must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each hospital to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs already require hospitals to have an infection prevention and control program (IPCP) and an infection preventionist (IP). The IPCP must have methods to prevent and control the transmission of infection within the hospital and between the hospital and other settings. Thus, all 5,194 hospitals should already have infection prevention and control policies and procedures. However, each hospital would need to review their current policies and procedures and modify them, if necessary, to ensure compliance with all of the requirements in this IFC, especially that their policies and procedures cover all of the eligible facility staff identified in this IFC. Based upon our experience with hospitals, we believe many hospitals have already developed policies and procedures requiring COVID–19 vaccination for staff. Since we have no reliable means to estimate the number of hospitals that may have already addressed COVID–19 vaccination of their staff, we will base our estimate for these requirements on all 5,194 hospitals.

We believe these activities would be performed by the IP, the director of nursing (DON), and an administrator. The IP would need to research COVID–19 vaccines, modify the policies and procedures, as necessary, and work with the DON and administrator to develop the policies and procedures and obtain appropriate approval. For the IP, we estimate these activities would require 8 hours. According to Table 3, the IP's total hourly cost is $79. Thus, for each hospital, the burden for the IP would be 8 hours at a cost of $632 (8 hours × 79). For the IPs in all 5,194 hospitals, the burden would be 41,552 hours (8 hours × 5,194) at an estimated cost of $3,282,608 (632 × 5,194).

As discussed above, the revision and approval of these policies and procedures would also require activities by the DON and an administrator. We believe these activities would require 2 hours each for the DON and an administrator. According to Table 3, the total adjusted hourly wage for both the DON and an administrator is $122. Hence, for each hospital, the burden would be 4 hours (2 × 2) at an estimated cost of $488 (4 × $122). The total burden for all 5,194 hospitals would be 20,776 hours (4 × 5,194) at an estimated cost of $2,534,672 (5,194 × 488).

Therefore, for all 5,194 hospitals, the total burden for the requirements for policies and procedures is 62,328 hours (41,552 + 20,776) at an estimated cost of $5,817,280 (3,282,608 + 2,534,672).

2. Documentation and Storage

Section 482.42(g) also requires hospitals to track and securely maintain the required documentation of staff COVID–19 vaccination status. Any burden for modifying the hospital's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation an adjusted hourly wage of $79 for each employee. According to Table 3, hospitals have 6,070,000 employees. We could not locate a reliable number for critical access hospital (CAH) employees so they are included here with the hospital employees. Hence, the burden for these documentation requirements for all 5,194 hospital and 1,358 CAHs would be 505,631 (0.0833 × 6,070,000) hours at an estimated cost of $39,944,849 (505,631 × 79).

Therefore, the total burden for this rule for all 5,194 hospitals and 1,358 CAHs (documentation burden only) would be 567,959 (62,328 + 505,631) hours at an estimated cost of $45,762,129 (5,817,280 + 39,944,849).

The requirements and burden will be submitted to OMB as an emergency reinstatement of an existing OMB control number 0938–0328.

E. ICRs Regarding the Development of Policies and Procedures for LTC Facilities § 483.80(i), ''COVID–19 Vaccination of Facility Staff''

1. Policies and Procedures

At § 483.80(i), we require LTC facilities to develop and implement policies and procedures to ensure their staff are vaccinated for COVID–19 and that appropriate documentation of those vaccinations are tracked and maintained. The LTC facility must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each LTC facility to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 483.80(d)(1) and (2) already require LTC facilities to have policies and procedures to educate, offer, and document vaccination status for residents regarding the influenza and pneumococcal immunizations. In addition, § 483.80(d)(3) requires LTC facilities to educate, offer, and document the vaccination status for residents and staff for the COVID–19 immunizations. Based upon our experience with LTC facilities, we believe some facilities have already developed policies and procedures requiring COVID–19 vaccination for staff, including COVID–19 vaccine mandates. However, we have no reliable means to estimate the number or percentage of LTC facilities that have already mandated vaccination. Hence, we will base our estimate for this ICR on all 15,401 LTC facilities.

Each LTC facility would need to review its policies and procedures for § 483.80(d) and modify them to comply with the requirements in this rule at § 483.80(i) and obtain the appropriate review and approval. This would require conducting research and revising the policies and procedures as needed. We believe these activities

would be performed by the infection preventionist (IP), director of nursing (DON), and medical director for the first year and the IP in subsequent years as analyzed below.

The IP would need to work with the DON and medical director to revise and finalize the policies and procedures. For the IP, we estimate this would require 2 hours initially to perform research and revise the policies and procedures to meet these requirements. According to Table 3, the IP's total hourly cost is $69. Thus, for each LTC facility, the burden for the IP would be 2 hours at a cost of $138 (2 hours × 69). For the IPs in all 15,401 LTC facilities, the burden would be 30,802 hours (2 hours × 15,401 facilities) at an estimated cost of $2,125,338 (138 × 15,401).

As discussed above, the revision and approval of these policies and procedures would also require activities by the DON and medical director. Both the DON and medical director would need to have meetings with the IP to discuss the revision, evaluation, and approval of the policies and procedures. We estimate this would require 1 hour for both the DON and medical director. According to Table 3, the total hourly cost for the DON is $96. The burden in the first year for the DON in each LTC facility would be 1 hour at an estimated cost of $96 (1 hour × 96). The burden would be 15,401 hours (1 × 15,401) at an estimated cost of $1,478,496 (96 × 15,401) for all LTC facilities.

For the medical director, we have estimated the revision of policies and procedures would also require 1 hour. According to the chart above, the total hourly cost for the medical director is $171. For each LTC facility, this would require 1 hour for the medical director during the first year at an estimated cost of $171 (1 hour × $171). the burden for all LTC facilities would be 15,401 hours (1 × 15,401) at an estimated cost of $2,633,571 (171 × 15,401).

Therefore, for all 15,401 LTC facilities in the first year, the estimated burden for the policies and procedures requirement would be 61,604 hours (30,802 + 15,401 + 15,401) at a cost of $6,237,405 (2,125,338 + 1,478,496 + 2,633,571).

2. Documentation and Storage

Section 483.80(i) also requires LTC facilities to track and securely maintain the required documentation of staff COVID–19 vaccination status. Any burden for modifying the facility's policies and procedures for these activities is already accounted for above. The PRA package submitted under OMB Control No. 0938–1363 already provides for the documentation burden for the IP for the LTC facility's infection prevention and control program (IPCP) under which the requirements in this rule will also be located. We believe the burden for the documentation requirements in this rule should be included in that burden. Therefore, we will not assess any additional burden for the documentation requirements in this rule.

The requirements and burden will be submitted to OMB under OMB control number 0938–1363 (expiration date June 30, 2022).

F. ICRs Regarding the Development of Policies and Procedures for PRTFs § 441.151(c), ''COVID–19 Vaccination of Facility Staff''

1. Policies and Procedures

Section 441.151(c) requires psychiatric residential treatment facilities (PRTFs) to develop and implement policies and procedures to ensure their staff are vaccinated for COVID–19 and that appropriate documentation of those vaccinations are tracked and maintained. The PRTF must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each PRTF to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations for PRTFs do not address infection prevention and control or vaccinations. Hence, although we believe that at least some PRTFs have already addressed COVID–19 vaccination of their staff, we will assess the burden for all 357 PRTFs.

We believe these activities would be performed by an RN and an administrator. According to Table 3, an RN's total hourly cost is $74. Since there are not any current requirements that address COVID–19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each PRTF, the burden for the RN would be 8 hours at a cost of $592 (8 hours × 74). For all 357 PRTFs, the burden would be 2,856 hours (8 hours × 357) at an estimated cost of $211,344 (592 × 357).

As discussed above, the revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 3, the total hourly cost for the administrator is $122. Hence, for each PRTF, the burden would be 2 hours at an estimated cost of $244 (2 × 122). For all 357 PRTFs, the total burden would be 714 hours (2 × 357) at an estimated cost of $87,108 (357 × 244).

Thus, the total burden for all 357 PRTFs to comply with the policies and procedures requirements in this IFC for policies and procedures is 3,570 hours (2,856 + 714) at an estimated cost of $298,452 (211,344 + 87,108).

2. Documentation and Storage

Section 441.151(c) also requires PRTFs to track and securely maintain the required documentation of staff COVID–19 vaccination status. Any burden for modifying the facility's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation an adjusted hourly wage of $74 for each employee. According to Table 3, PRTFs have 30,000 employees. Hence, the burden for these documentation requirements for all 357 PRTFs would be 2,499 (0.0833 × 30,000) hours at an estimated cost of $184,926 (2,499 × 74).

Therefore, the total burden for all 357 PRTFs for this rule would be 6,069 (3,570 + 2,499) hours at an estimated cost of $483,378 (298,452 + 184,926)

The requirements and burden will be submitted to OMB under OMB control number 0938–0833 (expiration date May 31, 2022).

G. ICRs Regarding the Development of Policies and Procedures for ICFs-IID § 483.430(f), ''COVID–19 Vaccination of Facility Staff''

1. Policies and Procedures

At § 483.430(f), we require ICFs-IID to develop and implement policies and procedures to ensure their staff are vaccinated for COVID–19 and that appropriate documentation of those vaccinations are tracked and maintained. The ICFs-IID must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each ICFs-IID to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 483.470(l) Standard: Infection control requires that the ICFs-IID must provide a sanitary environment to avoid sources and transmission of infections. The facility must also implement successful corrective action in affected problem areas, maintain a record of incidents and corrective actions related to infections, and prohibit employees with symptoms or sign of a communicable

disease from direct contact with clients and their food. Hence, ICFs-IID should already have policies and procedures for infection prevention and control.

We believe these activities would be performed by the RN. According to Table 3, an RN's total hourly cost is $69. Since there are not any current requirements that address COVID–19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each ICFs-IID, the burden for the RN would be 8 hours at a cost of $552 (8 hours × 69). For all 5,780 ICFs-IID, the burden would be 46,240 hours (8 hours × 5,780) at an estimated cost of $3,190,560 (552 × 5,780).

As discussed above, the revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 3, the total hourly cost for the administrator is $96. Hence, for each ICFs-IID, the burden would be 2 hours at an estimated cost of $192 (2 × 96). For all 5,780 ICFs-IID, the total burden would be 11,560 hours (2 × 5,780) at an estimated cost of $1,109,760 (5,780 × 192).

Thus, the total burden for all 5,780 ICFs-IID to comply with the requirements for policies and procedures is 57,800 hours (46,240 + 11,560) at an estimated cost of $4,300,320 (3,190,560 + 1,109,760).

2. Documentation and Storage

Section 483.430(f) also requires ICFs-IID to track and securely maintain the required documentation of staff COVID–19 vaccination status. Any burden for modifying the facility's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $69 for each employee. According to Table 3, ICFs-IID have 80,000 employees. Hence, the burden for these documentation requirements for all 5,780 ICFs-IID would be 6,664 (0.0833 × 80,000) hours at an estimated cost of $459,816 (6,664 × $69).

Therefore, the total burden for all 5,780 ICFs-IID for this rule would be 64,464 (57,800 + 6,664) hours at an estimated cost of $4,760,136 (4,300,320 + 459,816).

The requirements and burden will be submitted to OMB under OMB control number 0938–1402 (expiration date September 30, 2024).

H. ICRs Regarding the Development of Policies and Procedures for HHAs § 484.70(d), ''COVID–19 Vaccination of Home Health Agency Staff''

1. Policies and Procedures

At § 483.70(d), we require HHAs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID–19 and that appropriate documentation of those vaccinations are tracked and maintained. The HHA must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each HHA to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 483.70, Condition of participation: Infection prevention and control require each HHA to maintain and document an infection control program to prevent and control infections and communicable diseases. The HHA must follow accepted standards of practice, including the use of standard precautions to prevent the transmission of infections and communicable diseases. Thus, all HHA should already have infection prevent and control policies and procedures, but they likely do not comply with all of the requirements in this IFC.

All HHAs would need to review their current policies and procedures and modify them to comply with all of the requirements in § 483.70(d), as set forth in this IFC. While we believe that many HHAs have already addressed COVID–19 vaccination with their staff, we have no reliable means to estimate that number. Therefore, we will assess the burden for these requirements for all 11,649 HHAs. We believe these activities would be performed by the RN and an administrator. According to Table 3, an RN in home health services total hourly cost is $73. Since there are not any current requirements that address COVID–19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each HHA, the burden for the RN would be 8 hours at a cost of $584 (8 hours × 73). For all 11,649 HHAs, the burden would be 93,192 hours (8 hours × 11,649) at an estimated cost of $6,803,016 (584 × 11,649).

As discussed above, the revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 3, the total hourly cost for the administrator in home health services is $97. Hence, for each HHA, the burden would be 2 hours at an estimated cost of $194 (2 × 97). For all 11,649 HHAs, the total burden would be 23,298 hours (2 × 11,649) at an estimated cost of $2,259,906 (11,649 × 194).

Thus, the total burden for all 11,649 HHAs to comply with the policies and procedures requirements for policies and procedures is 116,490 hours (93,192 + 23,298) at an estimated cost of $9,062,922 (6,803,016 + 2,259,906).

2. Documentation and Storage

Section 483.70(d) also requires HHAs to track and securely maintain the required documentation of staff COVID–19 vaccination status. Any burden for modifying the agency's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $73 for each employee. According to Table 3, HHAs have 2,110,000 employees. Hence, the burden for these documentation requirements for all 11,649 HHAs would be 175,763 (0.0833 × 2,110,000) hours at an estimated cost of $12,830,699 (175,763 × 73).

Therefore, the total burden for all 11,649 HHAs for this rule would be 292,253 (116,490 + 175,763) hours at an estimated cost of $21,893,621 (9,062,922 + 12,830,699).

The requirements and burden will be submitted to OMB under OMB control number 0938–1299 (expiration date June 30, 2024).

I. ICRs Regarding the Development of Policies and Procedures for CORFs § 485.70(n), ''COVID–19 Vaccination of Facility Staff''

1. Policies and Procedures

At § 485.70(n), we require CORFs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID–19 and that appropriate documentation of those vaccinations are tracked and maintained. Each CORF must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each CORF to develop the policies and procedures needed to satisfy all of the requirements in this section. This IFC requires CORF staff to receive the COVID–19 vaccine unless medically contraindicated as determined by a physician, advance practice registered nurse, or physician

assistant acting within their respective scope of practice as defined by and in accordance with all applicable State and local laws. Based upon our experience with CORFs, we believe some facilities have already developed policies and procedures requiring COVID–19 vaccination for staff unless medically contraindicated. However, each CORF will need to review their current policies and procedures and modify them, if necessary, to ensure compliance with the requirements in this IFC, especially that their policies and procedures cover all of the organization staff identified in this IFC. Hence, we will base our estimate for this ICR on all 159 CORFs. The CORF's governing body appoints an administrator who implements and enforces the facility's policies and procedures. Hence, we believe activities associated with this IFC would be performed by the administrator as analyzed below. The governing body would also need to review these policies and procedures, which would be included in its ''legal responsibility for establishing and implementing policies regarding the management and operation of the facility.''

The administrator would conduct research to either modify or develop policies and procedures. For the administrator, we estimate this would require 8 hours initially to perform research and revise or develop the policies and procedures to meet these requirements. According to Table 3, the administrator's total hourly cost is $98. Thus, for each CORF, the burden for the administrator would be 8 hours at a cost of $784 (8 × 98). For the administrators in all 159 organizations, the burden would be 1,272 hours (8 × 159) at an estimated cost of $124,656 (784 × 159).

The administrator would need to spend time attending governing body meetings to discuss and obtain approval for the policies and procedures; however, that would be a usual and customary business practice. Therefore, activities for the administrator associated with governing body approval for the policies and procedures are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

2. Documentation and Storage

Section 485.70(n) also requires CORFs to track and securely maintain the required documentation of staff COVID–19 vaccination status. Any burden for modifying the facility's policies and procedures for these activities is already accounted for above. We believe that this would require an administrator 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $98 for each employee. According to Table 3, CORFs have 10,000 employees. Hence, the burden for these documentation requirements for all 159 CORFs would be 833 (0.0833 × 10,000) hours at an estimated cost of $81,634 (833 × 98).

Therefore, the total burden for all 159 CORFs for this rule would be 2,105 (1,272 + 833) hours at an estimated cost of $206,290 (124,656 + 81,634).

The requirements and burden will be submitted to OMB under OMB control number 0938–1091 (expiration date November 30, 2022).

J. ICRs Regarding the Development of Policies and Procedures for CAHs § 485.640(f), ''COVID–19 Vaccination of CAH Staff'

1. Policies and Procedures

At § 485.640(f), we require critical access hospitals (CAHs) to develop and implement policies and procedures to ensure their staff are vaccinated for COVID–19 and that appropriate documentation of those vaccinations are tracked and maintained. The CAH must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each CAH to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs already require CAHs to have an infection prevention and control program (IPCP) and an infection preventionist (IP). The IPCP must have methods to prevent and control the transmission of infection within the hospital and between the hospital and other settings. Thus, all 1,358 CAHs should already have infection prevention and control policies and procedures. However, each CAH would need to review their current policies and procedures and modify them, if necessary, to ensure compliance with all of the requirements in this IFC, especially that their policies and procedures cover all of the eligible facility staff identified in this IFC. Based upon our experience with CAHs, we believe many CAHs have already developed policies and procedures requiring COVID–19 vaccination for staff. Since we have no reliable means to estimate the number of CAHs that may have already addressed COVID–19 vaccination of their staff, we will base our estimate for these requirements on all 1,358 CAHs.

We believe these activities would be performed by the IP, the director of nursing (DON), and an administrator. The IP would need to research COVID–19 vaccines, modify the policies and procedures, as necessary, and work with the DON and administrator to develop the policies and procedures and obtain appropriate approval. For the IP, we estimate these activities would require 8 hours. According to Table 3, the IP's total hourly cost is $79. Thus, for each hospital, the burden for the IP would be 8 hours at a cost of $632 (8 hours × 79). For the IPs in all 1,358 CAHs, the burden would be 10,864 hours (8 hours × 1,358) at an estimated cost of $858,256 (632 × 1,358).

As discussed above, the revision and approval of these policies and procedures would also require activities by the DON and an administrator. We believe these activities would require 2 hours each for the DON and an administrator. According to Table 3, the total adjusted hourly wage for both the DON and an administrator is $122. Hence, for each CAH the burden would be 4 hours (2 × 2) at an estimated cost of $488 (4 × $122). The total burden for all 1,358 CAHs would be 5,432 hours (4 × 1,358) at an estimated cost of $662,704 (1,358 × 488).

Therefore, for all 1,358 CAHs the total burden for the requirements for policies and procedures is 16,296 hours (10,864 + 5,432) at an estimated cost of $1,520,960 ($858,256 + $662,704).

2. Documentation and Storage

Section 485.640(f) also requires CAHs to track and securely maintain the required documentation of staff COVID–19 vaccination status. Any burden for modifying the CAH's policies and procedures for these activities is already accounted for above. Since we were unable to located a reliable number for CAH employees, the documentation burden for CAHs resulting from the documentation requirement in this rule is included in the hospitals' burden above.

The requirements and burden for CAHs without DPUs will be submitted to OMB under OMB control number 0938–1043 (expiration date March 31, 2024). The requirements and burden for CAHs with DPUs will be submitted to OMB under OMB control number 0938–0328(expired).

K. ICRs Regarding the Development of Policies and Procedures for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (Organizations) § 485.725(f), ''COVID–19 Vaccination of Organization Staff''

1. Policies and Procedures

At § 485.725(f), we require organizations to develop and implement policies and procedures to ensure their staff are vaccinated for COVID–19 and the appropriate documentation is tracked and maintained. The organization must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each organization to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 485.725(a) require organizations to establish an infection-control committee of representative professional staff with overall responsibility for infection control. This committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure compliance with those policies and procedures. Based upon these requirements and our experience with organizations, we believe some organizations have already developed policies and procedures requiring COVID–19 vaccination for staff unless medically contraindicated. However, since we have no reliable means to estimate how many organizations have done this, we will assess the burden for all 2,078 organizations. All organizations would need to review their current policies and procedures and modify them, if necessary, to ensure compliance with the requirements in this IFC.

The types of therapists at each organization vary depending upon the services offered. For the purposes of determining the COI burden, we will assume that the therapist is a physical therapist. We believe activities associated with this IFC would be performed by a physical therapist and administrator. A physical therapist would need to conduct research on the COVID–19 vaccines and then develop or modify policies and procedures that comply with the requirements in this IFC. The physical therapist would need to work with an administrator to make the necessary revisions. For the physical therapist, we estimate this would require 8 hours to perform research and revise or develop the policies and procedures to meet these requirements. According to Table 3, the physical therapist's total hourly cost is $84. Thus, for each organization, the burden for the physical therapist would be 8 hours at a cost of $672 ($8 \times 84$). For the physical therapists in all 2,078 organizations, the burden would be 16,624 hours ($8 \times 2{,}078$) at an estimated cost of $1,396,416 ($672 \times 2{,}078$).

As discussed above, the revision and approval of these policies and procedures would also require activities by the administrator. The administrator would need to have meetings with the physical therapist to discuss the revisions and draft any necessary policies and procedures, as well as approve the final policies and procedures. We estimate this would require 2 hours for the administrator. According to Table 3, the total hourly cost for the administrator is $98. The burden for the administrator in each organization would be 2 hours at an estimated cost of $196 ($2 \times 98$). For the administrators in all 2,078 organizations, the burden would be 4,156 hours ($2 \times 2{,}078$) at an estimated cost of $407,288 ($4{,}156 \times 98$).

Therefore, for all 2,078 organizations, the total burden for the requirements for policies and procedures is 20,780 hours (16,624 + 4,156) at an estimated cost of $1,803,704 (1,396,416 + 407,288).

2. Documentation and Storage

Section 485.725(f) also requires organizations to track and securely maintain the required documentation of staff COVID–19 vaccination status. Any burden for modifying the organization's policies and procedures for these activities is already accounted for above. We believe that this would require a physical therapist 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $84 for each employee. According to Table 3, these organizations have 10,000 employees. Hence, the burden for these documentation requirements for all 2,078 organizations would be 833 ($0.0833 \times 10{,}000$) hours at an estimated cost of $69,972 ($833 \times 84$).

Therefore, the total burden for all 2,078 organizations for this rule would be 21,613 (20,780 + 833) hours at an estimated cost of $1,873,676 (1,803,704 + 69,972).

The requirements and burden will be submitted to OMB under OMB control number 0938–0273 (expiration date June 30, 2024).

L. ICRs Regarding the Development of Policies and Procedures for CMHCs § 485.904(c), ''COVID–19 Vaccination of Center Staff''

1. Policies and Procedures

At § 485.904(c), we require CHMCs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID–19 and that appropriate documentation of those vaccinations are tracked and maintained. Each facility must maintain documentation of their staff's vaccination status. Also, each facility must have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each CHMC to develop the policies and procedures needed to satisfy all of the requirements in this section. Based upon our experience with CHMCs, we believe some centers have already developed policies and procedures requiring COVID–19 vaccination for staff unless medically contraindicated. However, since we do not have a reliable means to estimate how many CMHCs have done so, we will estimate the burden based on all 129 CHMCs.

Each CMHC will need to review their current policies and procedures and modify them, if necessary, to ensure compliance with the requirements in this IFC. Based on these requirements and our experience with CHMCs, we believe these activities would be performed by the CHMC administrator and a mental health counselor. The administrator would conduct research regarding the COVID–19 vaccines and then either modify or develop the policies and procedures necessary to comply with the requirements in this IFC. The administrator would send any recommendations for changes or additional policies or procedures to the mental health counselor. The administrator and mental health clinician would need to make the necessary revisions and draft any necessary policies and procedures. For the administrator, we estimate this would require 8 hours initially to perform research and revise or develop the policies and procedures to meet these requirements. According to Table 3, the administrator's total hourly cost is $113. Thus, for each CMHC, the burden for the administrator would be 8 hours at a cost of $904 ($8 \times 113$). The burden for the administrators in all 129 CHMCs would be 1,032 hours (8×129) at an estimated cost of $116,616 ($904 \times 129$).

As discussed above, the revision and approval of these initial policies and procedures would also require activities

by the mental health counselor. The administrator would need to have meetings with the mental health counselor to discuss the revisions and draft any necessary policies and procedures. We estimate this would require 2 hours for the mental health counselor. According to Table 3, the total hourly cost for the mental health counselor is $118. The burden for the mental health counselor in each CHMC would be 2 hours at an estimated cost of $236 (2 × 118). For the mental health counselors in all 129 CMHCs, the burden would be 258 hours (2 × 129) at an estimated cost of $30,444 (129 × 236).

Therefore, for all 129 CMHCs, the total burden for the requirements for policies and procedures is 1,290 hours (1,032 + 258) at an estimated cost of $147,060 (116,616 + 30,444).

2. Documentation and Storage

Section 485.904(c) also requires CMHCs to track and securely maintain the required documentation of staff COVID–19 vaccination status. Any burden for modifying the center's policies and procedures for these activities is already accounted for above. We believe that this would require an administrator 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $113 for each employee. According to Table 3, CMHCs have 140,000 employees. Hence, the burden for these documentation requirements for all 129 CMHCs would be 11,662 (0.0833 × 140,000) hours at an estimated cost of $1,317,806 (11,662 × 113).

Therefore, the total burden for all 129 CMHCs for this rule would be 12,952 (1,290 + 11,662) hours at an estimated cost of $1,464,866 (147,060 + 1,317,806).

The requirements and burden will be submitted to OMB under OMB control number 0938–1245 (expiration date April 30, 2023).

M. ICRs Regarding the Development of Policies and Procedures for HIT Suppliers § 486.525(c), ''COVID–19 Vaccination of Facility Staff''

1. Policies and Procedures

Section 486.525(c) requires home infusion therapy (HIT) suppliers to develop and implement policies and procedures to ensure their staff are vaccinated for COVID–19 and that appropriate documentation of those vaccinations are tracked and maintained. The HIT supplier must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each HIT supplier to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 486.525 already require that HIT suppliers provide their services in accordance with nationally recognized standards of practice. Thus, we believe most HIT suppliers should already have infection prevention and control policies and procedures, including COVID–19 vaccination. However, we have no reliable means to estimate how many suppliers have done so. Thus, we will base our burden estimate on all 337 HIT suppliers.

All HIT suppliers would need to review their current policies and procedures and develop or modify them to comply with all of the requirements in § 486.525(c) as set forth in this IFC. We believe these activities would be performed by the RN and an administrator working for the HIT supplier. According to Table 3, an RN working with for a HIT supplier would have a total hourly cost of $73. Since there are not any current requirements that address COVID–19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each HIT supplier, the burden for the RN would be 8 hours at a cost of $584 (8 hours × 73). For all 337 HIT suppliers, the burden would be 2,696 hours (8 hours × 337) at an estimated cost of $24,601 (337 × 73).

The development and/or revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 3, the total hourly cost for the administrator working for a HIT supplier is $97. Hence, for each HIT supplier, the burden would be 2 hours at an estimated cost of $194 (2 × 97). For all 337 HIT suppliers, the total burden for the administrator would be 674 hours (2 hours × 337) at an estimated cost of $65,378 (337 × 194).

Therefore, for all 337 HIT suppliers, the total burden for the requirements for policies and procedures is 3,370 hours (2,696 + 674) at an estimated cost of $89,979 (24,601 + 65,378).

2. Documentation and Storage

Section 486.525(c) also requires HIT suppliers to track and securely maintain the required documentation of staff COVID–19 vaccination status. Any burden for modifying the supplier's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $73 for each employee. According to Table 3, HIT suppliers have 20,000 employees. Hence, the burden for these documentation requirements for all 337 HIT suppliers would be 1,666 (0.0833 × 20,000) hours at an estimated cost of $121,618 (1,666 × 73).

Therefore, the total burden for all 337 HIT suppliers for this rule would be 5,036 (3,370 + 1,666) hours at an estimated cost of $211,597 (89,979 + 121,618).

The requirements and burden will be submitted to OMB under OMB control number 0938–855B (expiration date March 31, 2024).

N. ICRs Regarding the Development of Policies and Procedures for RHCs and FQHCs § 491.8(d), ''COVID–19 Vaccination of Staff''

1. Policies and Procedures

At § 491.8(d), we require RHCs/FQHCs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID–19 and that appropriate documentation of those vaccinations are tracked and maintained. Each RHC/FQHC must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each RHC/FQHC to develop the policies and procedures needed to satisfy all of the requirements in this section. This IFC requires clinic or center staff to receive the COVID–19 vaccine unless medically contraindicated as determined by a physician, advance practice registered nurse, or physician assistant acting within their respective scope of practice as defined by and in accordance with all applicable State and local laws. Based upon experience with RHCs/FQHCs, we believe some clinics or centers have already developed policies and procedures requiring COVID–19 vaccination for staff unless medically contraindicated. However, since we do not have a reliable means to estimate how many facilities have already done so, we will base the burden analysis for this estimate on all 15,317 RHC/FQHCs (4,933 RHCs and 10,384 FQHCs).

Each RHC/FQHC will need to review their current policies and procedures and modify them, if necessary, to ensure compliance with the requirements in this IFC, especially that their policies and procedures cover all of the clinic or center staff identified in this IFC. Current regulations require a physician,

nurse practitioner, and physician assistant to participate in the development, execution, and periodic review of the policies and procedures.[222] Moreover, the RHC/FQHC operates under the medical direction of a physician. Based on these requirements and our experience with RHCs/FQHCs, we believe activities associated with this IFC would be performed by the RHC administrator, physician, nurse practitioner, physician assistant, and medical director as analyzed below.

The administrator would conduct research to either modify or develop policies and procedures. The administrator would send any recommendations for changes or additional policies or procedures to the physician, nurse practitioner, and physician assistant. The administrator, physician, nurse practitioner, and physician assistant would need to make the necessary revisions and draft any necessary policies and procedures. The administrator would need to work with the medical director to obtain approval for the policies and procedures to be implemented. For the administrator, we estimate this would require 8 hours initially to perform research and revise or develop the policies and procedures to meet these requirements. According to Table 3, the administrator's total hourly cost is $108. Thus, for each RHC/FQHC, the burden for the administrator would be 8 hours at a cost of $864 (8 × 108). For the administrators in all 15,317 RHCs/FQHCs, the burden would be 122,536 hours (8 × 15,317) at an estimated cost of $13,233,888 (864 × 15,317).

As discussed above, the revision and approval of these initial policies and procedures would also require activities by the physician, nurse practitioner, physician assistant, and medical director. The administrator would need to have meetings with the physician, nurse practitioner, and physician assistant to discuss the revisions and draft any necessary policies and procedures. The administrator would also need to have meetings with the medical director to obtain approval for the policies and procedures. We estimate this would require 2 hours each for the physician, nurse practitioner, and physician assistant. For the medical director, we estimate 1 hour would be required to perform this function. According to Table 3, the total hourly cost for the physician is $212. The burden for the physician in each RHC/FQHC would be 2 hours at an estimated cost of $424 (2 × 212). For the physicians in all 15,317 RHCs/FQHCs, the burden would be 30,634 hours (2 × 15,317) at an estimated cost of $6,494,408 (424 × 15,317). The hourly cost for the nurse practitioner is $107. The burden for the nurse practitioner in each RHC/FQHC would be 2 hours at an estimated cost of $214 (2 × 107). For the nurse practitioners in all 15,317 RHCs/FQHCs, the burden would be 30,634 hours (2 × 15,317) at an estimated cost of $3,277,838 ($214 × 15,317). The hourly cost for the physician assistant is $111. The burden for the physician assistant in each RHC/FQHC would be 2 hours at an estimated cost of $222 (2 × 111). For the physician assistants in all 15,317 RHCs/FQHCs, the burden would be 30,634 hours (2 × 15,317) at an estimated cost of $3,400,374 (15,317 × 222). The hourly cost for the medical director is $212. The burden for the medical director in each RHC/FQHC would be 1 hour at an estimated cost of $212. For the medical directors in all 15,317 RHCs/FQHCs, the burden would be 15,317 hours (1 × 15,317) at an estimated cost of $3,247,204 (15,317 × 212).

Therefore, for all 15,317 RHCs/FQHCs, the estimated burden associated with the policies and procedures requirement would be 229,755 hours (122,536 + 30,634 + 30,634 + 30,634 + 15,317) at a cost of $29,653,712 (13,233,888 + 6,494,408 + 3,277,838 + 3,400,374 + 3,247,204).

2. Documentation and Storage

Section 491.8(d) also requires RHCs/FQHCs to track and securely maintain the required documentation of staff COVID–19 vaccination status. Any burden for modifying the clinic's or center's policies and procedures for these activities is already accounted for above. We believe that this would require an administrator 5 minutes or 0.0833 hours to perform the required documentation at an adjusted hourly wage of $108 for each employee. According to Table 3, RHCs have 40,000 employees and FQHCs have 110,000 employees for a total of 150,000 employees. Hence, the burden for these documentation requirements for all 15,317 RHCs and FQHCs would be 12,495 (0.0833 × 150,000) hours at an estimated cost of $1,349,460 (12,495 × 108).

Therefore, the total burden for all 15,317 RHCs and FQHCs for this rule would be 242,250 (229,755 + 12,495) hours at an estimated cost of $31,003,172 (29,653,712 + 1,349,460).

The requirements and burden will be submitted to OMB under OMB control number 0938–0334 (expiration date March 31, 2023).

O. ICRs Regarding the Development of Policies and Procedures for ESRD Facilities § 494.30(b), ''COVID–19 Vaccination of Facility Staff'

1. Policies and Procedures

Section 494.30(b) requires the ESRD facilities to develop and implement policies and procedures to ensure their staff are vaccinated for COVID–19 and that appropriate documentation of those vaccinations are tracked and maintained. The ESRD facility must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each ESRD facility to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 494.30 already require that ESRD facilities follow standard infection control precautions. Thus, all ESRD facilities should have infection prevention and control policies and procedures. We believe that many ESRD facilities have already addressed COVID–19 vaccination for their staff. However, we have no reliable means to estimate how many ESRD facilities have done so. Thus, we will base our burden estimate on all 7,893 ESRD facilities.

All ESRD facilities would need to review their current policies and procedures and develop or modify them to comply with all of the requirements in § 494.30(b) as set forth in this IFC. We believe these activities would be performed by the RN and an administrator. According to Table 3, an RN working with for an ESRD facility would have a total hourly cost of $73. Since there are not any current requirements that address COVID–19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each ESRD facility, the burden for the RN would be 8 hours at a cost of $584 (8 hours × $73). For all ESRD facilities, the burden would be 63,144 hours (8 hours × 7,893) at an estimated cost of $4,609,512 (7,893 × 584).

The development and/or revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 3, the total hourly cost for the administrator at an ESRD facility is $97. Hence, for each ESRD, the burden for the administrator would be 2 hours at an estimated cost of $194 (2 × 97). For all ESRD facilities, the total burden would be 15,786 hours

[222] 42 CFR 491.7.

(2 × 7,893) at an estimated cost of $1,531,242 (7,893 × 194). Thus, the total burden for all ESRD facilities for the policies and procedures requirement would be 78,930 hours (63,144 + 15,786) at an estimated cost of $6,140,754 ($4,609,512 + $1,531,242).

2. Documentation and Storage

Section 494.30(b) also requires ESRD facilities to track and securely maintain the required documentation of staff COVID–19 vaccination status. Any burden for modifying the facility's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation at an adjusted hourly wage of $73 for each employee. According to Table 3, ESRD facilities have 170,000 employees. Hence, the burden for these documentation requirements for all 7,893 ESRD facilities would be 14,161 (0.0833 × 170,000) hours at an estimated cost of $1,033,753 (14,161 × 73).

Therefore, the total burden for all 7,893 ESRD facilities for this rule would be 93,091 (78,930 + 14,161) hours at an estimated cost of $ 7,174,507 (6,140,754 + 1,033,753).

The requirements and burden will be submitted to OMB under OMB control number 0938–0386 (expiration date March 31, 2024).

Based upon the above analysis, the total burden for all of the ICRs in this IFC is 1,555,487 hours at an estimated cost of $136,088,221.

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TABLE 4: Summary of Information Collection Burdens

Regulation (§) - Provider or Supplier	OMB Control No.	No. of Respondents	No. of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Labor Costs ($)
416.51(c) - Ambulatory Surgical Centers (ASCs) – Policies and Procedures	0938-0266	6,071	6,071	11	67,010	4,929,652
416.51(c) - ASCs - Documentation	0938-0266	6,071	200.000	0.0833	16,660	1,282,820
418.60(d) Hospices – Policies and Procedures	0938-1067	5,556	5,556	10	55,560	4,867,056
418.60(d) Hospices – Documentation	0938-1067	5,556	340,000	0.0833	28,322	2,237,438
441.151(c) - Psychiatric Residential Treatment Facilities (PRTFs) – Policies and Procedures	0938-1384	357	357	10	3,570	298,452
441.151(c) – PRTFs - Documentation	0938-1384	357	30,000	0.0833	2,499	184,926
460.74(d) - Programs for All Inclusive Care for the Elderly (PACE) – Policies and Procedures	0938-1326	141	141	10	1,410	117,876
460.74(d) – PACE - Documentation	0938-1326	141	10,000	0.0833	833	61,642
482.42(g) – Hospitals – Policies and Procedures	0938-0328	5,194	5,194	12	62,328	5,817,280
482.42(g) – Hospitals - Documentation	0938-0328	5,194	6,070,000	0.0833	505,631*	39,944,849
483.80(i) - Long Term Care (LTC) –Facilities (SNFs and NFs) – Policies and Procedures **	0938-1363	15,401	15,401	4	61,604	6,237,405
483.430(f) - Intermediate Care Facilities for	0938-1402	5,780	5,780	10	57,800	4,300,320

Regulation (§) - Provider or Supplier	OMB Control No.	No. of Respondents	No. of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Labor Costs ($)
Individuals with Intellectual Disabilities (ICFs-IIDs) – Policies and Procedures						
483.430(f) – ICFs-IID - Documentation	0938-1402	5,780	80,000	0.0833	6,664	459,816
484.70(d) - Home Health Agencies (HHAs) – Policies and Procedures	0938-1299	11,649	11,649	10	116,490	9,062,922
484.70(d) – HHAs - Documentation	0938-1299	11,649	2,110,000	0.0833	175,763	12,830,699
485.70(n) - Comprehensive Outpatient Rehabilitation Facilities (CORFs) – Policies and Procedures	0938-1091	159	156	8	1,272	124,656
485.70(n) – CORFs - Documentation	0938-1091	159	10,000	0.0833	833	81,634
485.58(d) - Critical Access Hospitals (CAHs) – Policies and Procedures	0938-1043 and 0938-0328	1,358	1,358-	12	16,296	1,520,960
485.725(f) – Organizations Policies and Procedures	0938-0273	2,078	2,078	10	20,780	1,803,704
485.725(f) – Organizations - Documentation	0938-0273	2,078	10,000	0.0833	833	69,972
485.704(c) - Community Mental Health Centers (CMHCs) – Policies and Procedures	0938-1245	129	129	10	1,290	147,060
485.704(c) – CMHCs - Documentation	0938-1245	129	140,000	0.0833	11,662	1,317,806
486.525(c) - Home Infusion Therapy (HIT) Suppliers – Policies and Procedures	0938-1377	337	337	10	3,370	89,979
486.525(c) – HITs - Documentation	0938-1377	317	20,000	0.0833	1,666	121,618
491.8(d) - Rural Health Clinics	0938-0334	15,317	15,317	15	229,755	29,653,712

Regulation (§) - Provider or Supplier	OMB Control No.	No. of Respondents	No. of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Labor Costs ($)
(RHCs) and Federally Qualified Health Clinics (FQHCs) – Policies and Procedures						
491.8(d) – RHCs and FQHCs - Documentation	0938-0334	15,317	150,000	0.0833	12,495	1,349,460
494.30(b) - End Stage Renal Disease (ESRD) Facilities – Policies and Procedures	0938-0386	7,893	7,893	10	78,930	6,140,754
494.30(b) ESRD Facilities - Documentation	0938-0386	7,893	170,000	0.0833	14,161	1,033,753
Totals					**1,555,487**	**$136,088,221**

*We were not able to locate a reliable number for CAH employees only. The number for hospital employees includes both hospital and CAH employees.

**Since the documentation burden for the IPCP is already accounted for in the current PRA package, OMB Control No. 0938-1363, a separate burden for this rule was not assessed.

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If you comment on these information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this IFC.

Comments must be received on/by January 4, 2022.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

The COVID–19 pandemic has precipitated the greatest public health crisis in the U.S. since the 1918 Influenza pandemic. The population of older adults, and LTC facility residents in particular, have been hard hit by the impacts of the pandemic. Among those infected, the death rate for older adults age 65 or higher was hundreds of time higher than for those in their 20s during 2020.[223] Of the approximately 656,000 Americans estimated to have died from COVID–19 through September 10, 2021,[224] 30 percent are estimated to have died during or after an LTC facility stay, although these numbers are decreasing as vaccination rates increase in residents and staff as shown in the CDC Data Tracker. Despite the recent nation-wide surge in infections from the Delta variant of COVID–19, uptake of vaccines and other measures (masking, screening visitors, and social distancing in particular) to prevent COVID–19, in combination with available therapeutic options to treat, has reduced COVID–19-related patient deaths in all settings. But reductions in COVID–19-related morbidity and mortality depend critically on continued success in vaccination of all health care staff and patients. The May 13, 2021 COVID–19 IFC (86 FR 26306) required offering vaccination to residents and staff, but did not mandate vaccination. Recently, however the Departments of Defense and Veterans Affairs staff, and civilian Federal Government employees have become subject to requirements similar to those imposed in this rule.[225] This IFC will close a gap in current regulations for all categories of health care provider whose health and safety practices are directly regulated by CMS. Almost all CMS-regulated providers and suppliers disproportionately serve people who are older, disabled, chronically ill, or who have complex health care needs.[226] Because the health care sector has such widespread and direct contact with hundreds of millions of patients, clients, residents, and program participants, the protective scope of this rule is far broader than the health care staff that it directly affects.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the

[223] For updated data, see CDC daily updates of total deaths at *https://www.cdc.gov/nchs/nvss/vsrr/COVID19/index.htm,* and the Kaiser Family Foundation weekly updates on nursing home deaths at *https://www.kff.org/coronavirus-covid-19/issue-brief/state-covid-19-data-and-policy-actions/,* among other sources.

[224] *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[225] *https://www.va.gov/opa/pressrel/pressrelease.cfm?id=5703.*

[226] For data on the massive differences in healthcare usage by age, see the National Health Expenditure Date at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.*

Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared an RIA that, taken together with COI section and other sections of the preamble, presents to the best of our ability the costs and benefits of the rulemaking.

This RIA focuses on the overall costs and benefits of the rule, taking into account vaccination uptake to date or anticipated over the next year that is not due to this rule, and estimating the likely additional effects of this rule on both provider staff and the patients with whom they come in contact. We analyze both the costs of the required actions and the payment of those costs. As intended under these requirements, this RIA's estimates cover only those costs and benefits that are likely to be the effects of this rule. There are also several unknowns that may affect current progress or this rule or both. These include the duration of strong vaccine protection with or without a booster shot and the possibility of new virus variants that reduce the effectiveness of currently authorized and approved vaccines. We cannot estimate the effects of each of the possible interactions among them, but throughout the analysis we point out some of the most important assumptions we have made and the possible effects of alternatives to those assumptions. The providers and suppliers regulated under this rule are diverse in nature, management structure, and size. That said, we believe that the costs faced by regulated entities will be very similar on a ''per person vaccinated'' basis. Tables 5 and 6 show the full scope of provider and supplier types, facility structures, and staff sizes, taking into account part-time staff (Table 5) and estimated staff turnover (Table 6). As explained earlier in the preamble, this rule includes facility contractors and consulting specialists as well as other persons providing part-time or occasional services to these providers and suppliers and their patients.

In Table 5 we provide a rough estimate of the likely number of full-time employees and other employees and contractors subject to this rule. The ''total staff'' number in the rightmost column is the number of individual staff directly affected at the time this rule takes effect (adding the number of full-time employees to the number of part-time employees, contractors, and other business persons who have recurring patient or staff interactions).

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TABLE 5: Estimates of Number of Staff by Type of Provider and Supplier (thousands)

Provider or Supplier Type	Number of Providers/Suppliers	Full-Time Employees (thousands)	Add-on Percent for Part-time Employees & Business Visitors	Number Part-time Employees & Business Visitors (thousands)	Total Staff Estimate (thousands)
Long Term Care (LTC) Facilities	15,401	950	10%	100	1,050
Skilled Nursing Care*	*	*	*	*	*
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID)	5,780	70	10%	10	80
Psychiatric Residential Treatment Facilities (PRTFs)	357	30	10%	-	30
Hospitals (inpatient)	5,194	5,520	10%	550	6,070
Hospitals (outpatient)**	**	**	**	**	**
Community Access Hospitals (CAHs)	**	**	**	**	**
Ambulatory Surgical Centers (ASCs)	6,071	180	10%	20	200
End-Stage Renal Disease (ESRD) Facilities	7,893	150	10%	20	170
Community Mental Health Centers (CMHCs)	129	130	10%	10	140
Comprehensive Outpatient Rehabilitation Facilities (CORFs)	159	10	10%	-	10
Federally Qualified Health Centers (FQHCs)	10,384	100	10%	10	110
Clinics, rehabilitation agencies, and public health agencies that provide outpatient physical therapy and speech-language services (Organizations)	2,078	10	10%	-	10
Rural Health Clinics (RHCs)	4,933	40	10%	-	40
Home Health Agencies (HHAs)	11,649	1,920	10%	190	2,110
Hospices	5,556	310	10%	30	340
Programs of All-Inclusive Care for the Elderly (PACE)	141	10	10%	-	10
Home Infusion Therapy (HIT) Suppliers	329	20	10%	-	20
TOTAL	76,054	9,450		940	10,390

* Included in total for Long Term Care (LTC) Facilities.
** Included in total for Hospitals.

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This rule presents additional difficulties in estimating both costs and benefits due to the high degree to which all current provider and supplier staff

have already received information about the benefits and safety of COVID–19 vaccination, and the rare serious risks associated with it. Despite this progress, the proportion of fully vaccinated health care staff has approached but not hit the 70 percent with significant variation among states. Moreover, among the general population more than 600,000 persons a day are currently being vaccinated with the first or second shot and about 100,000 a day have recovered from infection and are only in very rare cases still infectious. These changes reduce the risk to both health care staff and patients substantially, likely by about 20 million persons a month who are no longer sources of future infections.[227] This in turn reduces the number of newly infected cases (currently about 100,000 a day and decreasing rapidly). Yet another variable of importance is the increasing number of providers and suppliers that are mandating employee vaccination, and the increasing number of states that are doing so as well. To characterize the baseline scenario of no new regulatory action, from which we estimate the incremental impacts of the interim final rule, we assume that when Phase 1 of this IFC goes into effect, 75 percent of provider staff, 90 percent of LTC facility residents, and 80 percent of all other patients and clients will have been vaccinated, and that these rates will improve over time as a result of both this rule and the other factors previously discussed.[228]

These numbers leave a large range for the likely effects of this rule over time. They do indicate, however, that many cases of death or severe illness can be prevented by increasing the number of vaccinated persons, both for those vaccinated and for others they might otherwise infect. As estimated in Table 6, the number of unvaccinated health care workers still remains in the millions despite recent progress. As discussed later in this analysis, we use the concept of the value per statistical life and per statistical case to capture this major potential benefit, as recommended by the Office of the Assistant Secretary for Planning and Evaluation based on standard practices in cost-benefit analysis.[229]

One additional factor affecting our estimates is remaining life expectancy. Life expectancy varies by age, being about 40 years across an entire population, close to 80 years for a younger population, and a relatively fewer number of years for an older population. These numbers, of course, are overall averages and mask substantial differences by race and sex (among other factors), including access to affordable health care and prevalence of untreated or insufficiently controlled disease. Individuals with diabetes, for example, are disproportionately African American and disproportionately older, which leads to greater risks from kidney failure and other adverse health effects, including greater susceptibility to the ravages of COVID–19.[230] Health care staff of most types of providers and suppliers are of typical working ages. But hospital patients, LTC facility residents, ESRD patients treated for kidney failure, and most other patients are heavily weighted towards older ages and are disproportionately members of African American and Native American minority groups. This means that the morbidity and mortality reductions from this rule when they are adjusted for the age ranges affected disproportionally benefit racial minorities.

In particular, LTC facility residents are near the upper end of the age spectrum. For a statistically average LTC facility resident, the average pre-COVID–19 life expectancy if death occurs while in the facility is likely to be on the order of 3 years or fewer but taking into account residents who recover and leave the facility and those enrolled for skilled nursing services we estimate overall life expectancies to be about 5 years.[231] We also estimate that vaccination reduces the chance of infection by about 95 percent, and the risk of death from the virus to a fraction of 1 percent.[232] In Israel, of the first 2.9 million people vaccinated with two doses there were only about 50 infections involving severe conditions resulting from the virus after the 14th day and of these so few deaths that they were not reported in statistical summaries. These data also show that COVID–19 vaccines are effective for both older and younger recipients. Of those who have received a full primary vaccine series, after the 14th day after vaccination only 46 people over the age of 60 became infected and had a severe case, compared to 6 people under the age of 60. Given that these numbers are compared against 2.9 million recipients of the second dose, both rates are near zero.[233]

C. Anticipated Costs of the Interim Final Rule With Comment Period

We note that our cost estimates assume that all additional vaccination costs for providers and suppliers regulated by this rule are due to this rule. We estimate on this basis because we have no reliable way to estimate how much of these costs might be equally due to independent employer decisions, to other Federal standards, to State and local mandates, or even to individual personal choices.

In our cost estimates we cover all providers regulated by CMS for health and safety standards, but we often use LTC facilities for examples because they pose some of the greatest risks for COVID–19 morbidity and mortality. As documented subsequently in this analysis and in a research report on this issue, about 1.5 million individuals work in LTC facilities at any one time.[234] A number of these individuals work in multiple LTC facilities which may play additional roles in transmission.[235] [236] These individuals are at high risk both to become ill with COVID–19 and to transmit the SARS-

[227] These data are taken from or calculated from the CDC COVID Data Tracker. For example, in recent weeks the number of new daily cases has been gradually decreasing from about 150,000 to about 90,000. Once the disease runs its course, almost all these people will have recovered. Hence, we use the rough estimate that about 100,000 a day have recovered in recent weeks.

[228] Among long term care residents, the vaccinated percentage is now very close to 90 percent, but other categories of patients are undoubtedly lower. That said, patients are heavily age-skewed towards higher ages where vaccination percentages are higher.

[229] See ''Valuing COVID–19 Mortality and Morbidity Risk Reductions in U.S. Department of Health and Human Services Regulatory Impact Analyses, *https://aspe.hhs.gov/reports/valuing-covid-19-risk-reductions-hhs-rias.*

[230] For an NIH summary of the racial disparities, see *https://www.niddk.nih.gov/health-information/kidney-disease/race-ethnicity.*

[231] At age 80, the average life expectancy of a male is about 8 years and of females about 10 years, or an overall average of about 9 years. Long term care nursing home residents, however, have shorter life expectancies because they have severe health problems or would not have been admitted to a facility. For those who remain in a facility until death the average life expectancy is about 2 years. But some recover and leave so we have used 5 years as a reference point. See discussion at David B. Reuben, ''Medical Care for the Final Years of Life: When you're 83, It's not going to be 20 years,'' JAMA, Dec. 23, 2009, 2686–2694.

[232] For patients in skilled nursing facilities, average length of stay is less than a month. Hence, turnover is far higher.

[233] See Dvir Aran, Estimating real-world COVID–19 vaccine effectiveness in Israel using aggregated counts, medRxiv, February 28, 2021, at *https://www.medrxiv.org/content/10.1101/2021.02.05.21251139v3.full.pdf* and Noa Dagan et al, ''BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting,'' The New England Journal of Medicine, 2/24/2021, at *https://www.nejm.org/doi/full/10.1056/NEJMoa2101765.*

[234] Kaiser Family Foundation, COVID–19 and Workers at Risk: Examining the Long-Term Care Workforce, April 23, 2020, at *https://www.kff.org/coronavirus-covid-19/issue-brief/covid-19-and-workers-at-risk-examining-the-long-term-care-workforce/.*

[235] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7267626/.*

[236] *https://www.anderson.ucla.edu/faculty_pages/keith.chen/papers/WP_Nursing_Home_Networks_and_COVID19.pdf.*

CoV–2 virus to residents or visitors, or among themselves. Far more than most occupations, LTC facility work requires sustained close contact with multiple persons daily.

In Table 6 we present estimates of total numbers of staff individuals regulated under this rule, distinguishing between numbers at the beginning of a year and at any one time during the year, versus the much higher numbers when turnover is considered. In Table 6 we assume that the number departing each year is the same as the number entering each year, which is a reasonable approximation to changes in just a few years, but do not take account of the aging of the population over time. We note that our estimates do not include a deduction for the overlap among individuals who work in more than one LTC facility. We know that this number is substantial, but have no basis for estimating its precise magnitude and, more importantly, how it may change after this rule goes into effect and facilities change their staffing and hiring patterns. One recent study found about 17% of LTC nursing staff held second jobs, and another recent study found that about 5% held more than one LTC job. The second study, moreover, found that facilities with substantial staff sharing were disproportionally associated with as many as 49% of nursing home COVID–19 cases.[237]

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[237] See Courtney Harold Van Houtven, Nicole DePasquale, and Norma B. Coe, ''Essential Long-Term Care Workers Commonly Hold Second Jobs and Double- or Triple-Duty Caregiving Roles,'' Journal of the American Geriatrics Society, 27 April 2020, at *https://agsjournals.onlinelibrary.wiley.com/doi/full/10.1111/jgs.16509* and M. Keith Chen, Judith A. Chevalier, and Elisa F. Long, ''Nursing home staff networks and COVID–19,'' PNAS, January 5, 2021, at *https://www.pnas.org/content/118/1/e2015455118.*

TABLE 6: Estimates of Number and Vaccination Status of Staff by Provider and Supplier Type (thousands)

Provider or Supplier Type	Beginning of First Year	New Hires During First Year	Total for First Year	Percent Vaccinated by BOY	Number Vaccinated by BOY	Unvaccinated by BOY	Unvaccinated New Staff	Total To Be Vaccinated First Year
Long Term Care (LTC) Facilities	1,050	760	1,810	75%	790	260	40	300
Skilled Nursing Care*	*	*	*	*	*	*	*	*
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID)	80	60	140	75%	60	20	-	20
Psychiatric Residential Treatment Facilities (PRTFs)	30	10	40	80%	20	10	-	10
Hospitals (inpatient)	6,070	1,210	7,280	80%	4,860	1,210	60	1,270
Hospitals (outpatient)**	**	**	**	**	**	**	**	**
Community Access Hospitals (CAHs)	**	**	**	**	**	**	**	**
Ambulatory Surgical Centers (ASCs)	200	40	240	75%	150	50	-	50
End-Stage Renal Disease (ESRD) Facilities	170	30	200	75%	130	40	-	40
Community Mental Health Centers (CMHCs)	140	30	170	75%	110	30	-	30
Comprehensive Outpatient Rehabilitation Facilities (CORFs)	10	-	10	75%	10	-	-	-
Federally Qualified Health Centers (FQHCs)	110	20	130	75%	80	30	-	30
Clinics, rehabilitation agencies, and public health agencies that provide outpatient physical therapy and speech-language services (Organizations)	10	-	10	75%	10	-	-	-
Rural Health Clinics (RHCs)	40	10	50	75%	30	10	-	10
Home Health Agencies (HHAs)	2,110	420	2,530	75%	1,580	530	20	550
Hospices	340	70	410	75%	260	80	-	80
Program of All-Inclusive Care for the Elderly (PACE)	10	-	10	75%	10	-	-	-
Home Infusion Therapy (HIT) Suppliers	20	-	20	75%	20	-	-	-
TOTAL	10,390	2,660	13,050		8,120	2,270	120	2,390

* Included in total for Long Term Care (LTC) Facilities.
** Included in total for Hospitals.

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These figures are approximations, because none of the data that is routinely collected and published on resident populations or staff counts focus on numbers of individuals residing or working in the facility during the course of a year or over time. Depending on the average length of stay (that is, turnover) in different facilities,

an average population at any one time of, for example, 100 persons could be consistent with radically different numbers of individuals, such as 112 individuals in one facility if one person left each month and was replaced by another person, compared to 365 if one person left each day and was replaced that same day by another person.

As a specific example, we assume that about 90 percent of existing LTC facility residents and 75 percent of existing staff will have been vaccinated by the date Phase 1 of this IFC takes effect (we use the same or similar assumptions for all provider types). There will be many new persons in each category during the first full year of the regulation, and likely almost all of these will have been vaccinated elsewhere (for simplicity we also assume a base rate 95 percent for this group, almost all of whom will have previously worked in a health care facility requiring vaccination).

As presented in the third numeric column of Table 6, the total number of employees or otherwise compensated individuals working in all these different facilities over the course of a year is about 13 million persons, which is almost half again larger than the annual average number of staff shown in the first numeric column. A recent study, using data from detailed payroll records, found that median turnover rates for all nurse staff in long term care facilities is approximately 90 percent a year, although other estimates are far lower (see subsequent discussion).[238] We have not seen figures this high for other provider types but some may approach this level—home health care is well known for high turnover rates.[239] Of course, most of these persons will have been vaccinated through other means when they enter the facilities during the next year. That said, it is likely that there will be approximately 2.4 million staff at the beginning or during the first year after this rule is published who will require vaccination (rightmost column of Table 6), possibly preceded in some cases by counseling efforts or employer inducements.

While this IFC does not expressly require COVID–19 vaccine counseling or education, we anticipate that some providers and suppliers will conduct such activities as a part of their procedures for ensuring compliance with the provisions of this rule. Some staff counseling can take place in group settings and some will take place on a one-to-one level. What works best will depend on the circumstance of the employee and the best method for conveying the information and answering questions. Staff education, using CDC or FDA materials, can also take place in various formats and ways. Individualized counseling, staff meetings, posters, bulletin boards, and e-newsletters are all approaches that can be used. Informal education may also occur as staff go about their daily duties, and some who have been vaccinated may promote vaccination to others. Facilities may find that reward techniques, among other strategies, may help. For example, monetary or other benefits such as paid days off could be given to staff who agree to vaccination. Even simpler, the employer can bring vaccination providers onsite to vaccinate staff (or both staff and unvaccinated patients). Of importance in such efforts, the value of immunization as a crucial component of keeping patients healthy and well is already conveyed to staff about influenza and pneumococcal vaccines. COVID–19 vaccine persuasion can build upon that knowledge. The most important inducement will be the fear of job loss, coupled with the examples set by fellow vaccine-hesitant workers who are accepting vaccination more or less simultaneously.

One hundred percent success is unlikely. The HHS Guidelines for Regulatory Impact Analysis note that ''[i]n most cases, the analysis focuses on estimating the incremental compliance costs incurred by the regulated entities, assuming full compliance with the regulation, and government costs.'' These guidelines further recommend that ''[a]nalysts should consider the uncertainty associated with an assumption of full compliance and provide analysis of alternative assumptions, as appropriate.'' [240] In preparing this analysis, we have identified several significant sources of uncertainty for these full-compliance estimates, one of which stands out.

If only one health care provider in an area required staff vaccination, then those who refuse vaccination could quit and obtain employment at another location in the same field or type of position.[241] But with many employers already mandating vaccination, and with nearly all local (and distant) health care employers requiring vaccination under this rule, we expect that such effects will be minimized (with exceptions for medical or other exemptions as required by law). That said, currently there are endemic staff shortages for almost all categories of employees at almost all kinds of health care providers and supplier and these may be made worse if any substantial number of unvaccinated employees leave health care employment altogether. In this regard, we note that because CMS does not regulate health and safety in physician and dental offices, or in non-health care settings such as assisted living facilities, those entities may provide alternative places of employment for some of the staff currently working for providers and suppliers subject to this IFC who refuse vaccinations. On the other hand, staff shortages might be offset by persons returning to the labor market who were unwilling to work at locations where some other employees are unvaccinated and hence provide some risk, to those who have completed the primary vaccination series for COVID–19. Despite these uncertainties, we have developed an estimate of staffing disruption costs, primarily to provide a complete cost picture even if this element is particularly uncertain. We note that these costs and benefits are highly dependent on whether, for example, staff vaccination refusals in coming months are closer to 1 percent than to 10 percent, and the extent to which increased confidence in the safety of working in a health care setting leads to offsetting increases in the return of former health care employees to the workforce. Both variables, in turn, may depend in significant ways on the overall labor market and on the ability of telehealth measures to replace in-person staff to patient encounters. The net outcomes of staff turnover over time could easily exceed or offset the administrative and vaccination costs we have estimated. We welcome comments and information on these issues.

The techniques for staff counseling, education, and incentives are so numerous and varied that there is no simple way to estimate likely costs. Staff hesitancy may and likely will change over time as the benefits of vaccination become clear to increasing numbers of individuals working in health care

[238] Ashvin Gandhi *et al,* ''High Nursing Staff Turnover In Nursing Homes Offers Important Quality Information,'' Health Affairs, March 2021, pages 384–391.

[239] Ashvin Gandhi *et al,* ''High Nursing Staff Turnover In Nursing Homes Offers Important Quality Information,'' Health Affairs, March 2021, pages 384–391. Published estimates vary widely. For example, two recent sources said home health care staff turnover is about 65 percent. See *https://www.hcaoa.org/newsletters/caregiver-turnover-rate-is-652-2021-home-care-benchmarking-study* and *https://www.leadingage.org/sites/default/files/Direct%20Care%20Workers%20Report%20%20FINAL%20%282%29.pdf.*

[240] At *https://aspe.hhs.gov/sites/default/files/private/pdf/242926/HHS_RIAGuidance.pdf,* page 24.

[241] See *https://www.washingtonpost.com/local/covid-vaccine-mandate-hospitals-virginia/2021/10/01/b7976d16-21ff-11ec-8200-5e3fd4c49f5e_story.html,* and .

settings. For purposes of estimation, we assume that, on average, one hour of staff time or the equivalent will be devoted to counseling or incentives for each unvaccinated staff person, at the same average hourly cost of about $75 estimated for RNs in the Information Collection analysis. We assume that these efforts occur during paid working hours and that all costs will be borne by the facility. Since we estimate that about 2.4 million employees will need to be vaccinated (or replaced) in the first year (rightmost column of Table 6), most in the first two months after this rule is published, total costs would be about $180 million. This estimate assumes that the 2.4 million will be some mix of existing and replacement staff. For example, if 95% of the existing unvaccinated staff were vaccinated, and 5% of the unvaccinated staff terminated, then in addition to the normal turnover of 2.7 million new hires (second column of Table 6) an additional 114 thousand ($.05 \times 2{,}270$) persons would need to be hired, with 95% of them already fully vaccinated and the remainder getting vaccinated as a condition of hiring. For purposes of this estimate we ignore the existence of exemptions.

A third major cost component of compliance with this IFC is the vaccination, including both administration and the vaccine itself. We estimate that the average cost of a vaccination is what the government pays under Medicare: $\$20 \times 2 = \$40$ for two doses of a vaccine, and $\$20 \times 2$ for vaccine administration of two doses, for a total of $80 per employee. For purposes of estimation (and not reflecting any more knowledge than recent press accounts), we further assume that there will be a ''booster'' shot at the same cost, for a total vaccination cost of $120 per employee. While these vaccine costs are currently incurred by the Federal Government, we include them to provide an estimate of total costs, regardless of who pays. In addition, we expect that a significant amount of time—one hour on average—will be used per employee in vaccine planning, arrangement, and administration, and related activities for three vaccinations per currently unvaccinated employee. Together with the additional assumption that there will be an hour RN time or the equivalent needed for arranging or administering vaccination, at an average cost for that hour of $75, the total cost for vaccination compliance will be $195 per employee. We apply that cost to all currently unvaccinated employees. Like counseling and incentives, if 5% of the existing unvaccinated staff leave and are replaced by a slightly higher number of new hires than would otherwise be needed, a roughly equivalent fraction of the new hires will need to be vaccinated before they have patient contact. As a result, we estimate the total costs of vaccination to be approximately $466 million (2,390,000 unvaccinated employees x $195). We note again that these estimates do not reflect the factor that multiple vaccine mandates already do or will soon apply to many and perhaps most providers covered by our rule (employers' own self-imposed mandates, State and local mandates, and OSHA ETS, among others). This means the costs of this rule are overestimated due to this factor, a conservative assumption.

Our fourth and final major cost category is staffing and service disruptions. As discussed previously, it is possible there may be disruptions in cases where substantial numbers of health care staff refuse vaccination and are not granted exemptions and are terminated, with consequences for employers, employees, and patients. We do not have a cost estimate for those, since there are so many variables and unknowns, and it is unclear how they might be offset by reductions in current staffing disruptions caused by staff illness and quarantine once vaccination is more widespread. We believe, however, that the disruptive forces are weaker than the return to normality. As shown in Table 6, it is normal for there to be roughly 2.66 million new hires (column two) in the health care settings we address in this rule, compared to a baseline of roughly 10.4 million staff (column one). These new hires replace a roughly equal number of employees leaving for one reason or another. Health care providers are already in the business of finding and hiring replacement workers on a large scale. The terminated or self-terminated workers are not going to disappear. They still need to earn a living. Many of the non-clinical staff may will find employment situations in settings that are not subject to vaccination mandates. Cooks, for example, may migrate to restaurant jobs. But in those cases, a cook who would otherwise have been hired by a restaurant may find a newly vacant health care position requiring vaccination and accept (or more likely already have) vaccination. Similarly, nurses may find jobs in health care settings that are not subject to vaccination mandates, such as most schools or physician offices. But that means that nurses who would otherwise have been hired in schools or physician offices may find jobs in vacant jobs in health care settings requiring vaccination and accept (or more likely already have) vaccination. In a dynamic labor market such behaviors occur continuously on a massive scale. If net employment opportunities and job-seeking behaviors do not change (and there is no reason to believe they will), these continuous adjustments will leave health care providers and suppliers subject to this rule with their desired staff levels, and former employees who refused vaccination in jobs that do not require vaccination. Because job seeking and worker seeking are already operating on a massive scale in the health care sector, there is no reason to expect any massive new costs in such routine functions as advertising jobs, checking applicant employment history, familiarizing new employees with the nuances of the new employment setting, training, and all the other steps and costs involved in the normal workings of the labor market.

As an example of the likely magnitude of hiring costs, one analysis of direct hiring costs for workers in the long-term care sector (including LTC facilities, home health care, and ICFs-IID) found that the direct costs of hiring new workers was on average about $2,500 in 2004.[242] Assuming that this amount should be raised to $4,000 based on inflation since then, that a comparable estimate for higher skills health care professions would be $6,000, and that health care workers covered by this rule are half lower skilled and half higher skilled, the recruitment and hiring cost for additional hires equal to 5 percent of the normal annual hiring total of 2.4 million workers would be $600 million (an average of $\$5{,}000 \times 120{,}000$). (Costs could actually be lower because this study is almost a decade old and internet services have in recent years made recruitment and job application procedures far easier.)

An additional cost category may result from COVID–19-related staff shortages, discussed extensively earlier in this IFC. Although, as noted earlier, COVID-related staff shortages are occurring absent the rule due to numerous factors, such as infection, quarantine and staff illness. Shortages at their most acute prevent facilities from admitting as patients, clients, residents, or participants persons they would normally admit for treatment of diseases or conditions that would in many cases result in death or serious disability. We

[242] Dorie Seavey, The Cost of Frontline Turnover in Long-Term Care,'' Better Jobs Better Care Report, Washington, DC: Institute for the Future of Aging Services, American Association of Homes and Services for the Aging. 2004.

are not aware of any data that would enable a reasonably accurate estimate of the total medical morbidity and mortality involved, but it is certainly massive. While it is true that compliance with this rule may create some short-term disruption of current staffing levels for some providers or suppliers in some places, there is no reason to think that this will be a net minus even in the short term, given the magnitude of normal turnover and the relatively small fraction of that turnover that will be due to vaccination mandates. Moreover, the benefits of vaccination are not just the lives directly saved, but the resources that vaccination frees up because hospital, LTC facility, and rehabilitation beds are now available and because health care staff themselves are not being incapacitated or killed by COVID–19 infection. The data on cumulative COVID–19 cases among health care personnel show 677,000 cases (most of which incapacitated workers at least temporarily), and 2,200 deaths, all of which permanently eliminated those workers as sources of future care.[243]

Table 7 shows all of the costs that we have estimated. As previously explained, much and perhaps most of these costs would be incurred under other concurrent mandates, including employer-specific decisions, other Federal standards, and some State and local government mandates. Since these efforts overlap in scope, reach, and timing, there is no basis for assigning most of these costs to this rule or any other similar rule.

TABLE 7: Estimate of Total First Year Costs ($millions)

Cost Category	Estimate
Information Collection Costs	136
Counseling and Incentive Costs	180
Vaccination Costs	466
Disruptions to Staffing and Services	600
TOTAL	1,382

There are major uncertainties in these estimates. One obvious example is whether vaccine efficacy will last more than the approximately 1 year proven to date and whether boosters are needed.[244] Some in the scientific community believe that ''booster'' vaccinations after 6 or 8 months would be desirable to maintain a high level of protection against the predominant Delta version of the virus. Delta may be overtaken by other virus mutations, which creates another uncertainty. Booster vaccination or use of vaccines whose licenses or EUAs have been amended to address new variants would likely maintain the effectiveness of vaccination for residents and staff. At this time, as to second (and succeeding) year effects we assume no further major changes in vaccine effectiveness. Yet another uncertainty is treatment costs, with a recently announced antiviral pill that could potentially provide substantial reductions in severity of illness and subsequent treatment costs, on a time schedule as yet unknown.[245]

D. Anticipated Benefits of the Interim Final Rule With Comment Period

There will be more than 180 million staff, patients, and residents employed or treated each year in the facilities covered by this rule. In our analysis of first-year benefits of this rule we focus first on prevention of death among staff of facilities as well as on reduction in disease severity. Second, we focus on resulting benefits from avoiding infection by unvaccinated staff among patients served in these facilities, who are likely to benefit more substantially because patients receiving health care in such facilities are disproportionately older than working age adults and are therefore more susceptible to severe illness or death from COVID–19. A third group of beneficiaries are staff family members and caregivers and many other persons outside the health care settings who staff might subsequently infect if not vaccinated. We focus initially on LTC facilities because their residents and patients have been among the most severely affected by COVID–19 as well as illustrating all the estimating issues involved, but the same estimates, uncertainties, and calculations apply to all types of providers and suppliers in varying degrees.

HHS's Guidelines for Regulatory Impact Analysis outline a standard approach to valuing the health benefits of regulatory actions. The approach for valuing mortality risk reductions is based on the value per statistical life (VSL), which estimates individuals' willingness to pay (WTP) to avoid fatal risks. The approach to valuing morbidity risk reductions is based on measures of the WTP to avoid non-fatal risks when specific estimates are available, and based on measures of the duration and severity of the illness, including quality of life consequences, when suitable WTP estimates are not available.[246] Based on this approach, the Office of the Assistant Secretary for Planning and Evaluation published a report that develops an approach for valuing COVID–19 mortality and morbidity risk reductions.

[243] CDC Data Tracker, October 17, 2021 data, at *https://covid.cdc.gov/covid-data-tracker/#health-care-personnel.*

[244] For a discussion of this issue, see Sumathi Reddy, ''How Long Do Covid-19 Vaccines Provide Immunity?'', The Wall Street Journal, April 13, 2021, at *https://www.wsj.com/articles/how-long-do-covid-19-vaccines-provide-immunity-11618258094.*

[245] See Rebecca Robbins, ''Merck Says It Has the First Antiviral Pill Found to Be Effective Against Covid,'' The New York Times, October 1, 2021.

[246] As noted above, various populations are directly or indirectly affected by this rule. Lessened risk to patients due to staff vaccination, especially in a setting such as a LTC facility, is arguably an externality (a canonical market failure), and thus use of a VSL or VSLY estimate per avoided fatality or life extension does not represent a divergence from the concept of revealed preference. On the other hand, staff members' own risk raises the question of how to interpret their hesitation or unwillingness, in the absence of regulation, to accept an intervention that achieves extensive health protection for themselves, with little or no out-of-pocket cost, and ever-lessening time or inconvenience cost; a simplistic revealed-preference monetization of the rule's effect would be that it yields minimal or negative benefits for such staff members, even the ones for whom it prevents or reduces severity of COVID–19 infection. However, given the dynamic nature of the pandemic, it may be that long-run equilibrium for COVID–19 vaccines has not been reached, in which case the simplistic approach just mentioned may be misleading—and the use of a standard VSL or VSLY for staff-member risk evaluation may reflect misunderstandings of either vaccine risks or vaccine benefits.

In addition to the avoided death and human suffering, one of the major benefits of vaccination is that it lowers the cost of treating the disease among those who would might otherwise be infected and have serious morbidity consequences. The largest part of those costs is for hospitalization. As discussed later in the analysis we provide data on the average costs of hospitalization of these patients (it is, however, unclear as to how much that cost will change over time due to improving treatment options).

There is a potential offset to benefits that we have not estimated because we believe it is at this time not relevant in the U.S. If vaccine supplies did not meet all demands for vaccination, giving priority to some persons over others necessarily meant that some persons would become infected who would not have been infected had the priorities been reversed. In this case, however, the priority for older adults (virtually all of whom have risk factors) who comprise the majority of hospital inpatients and the vast majority of LTC facility residents has already been established and is largely met. This rule provides a priority for staff at a far lower risk of mortality and severe disease that benefits both groups.[247] It achieves this benefit because by preventing the spread of COVID–19 from provider and supplier staff, it actually provides a higher mortality and morbidity reduction for patients at far higher risk than the staff who become vaccinated.[248]

The HHS ''Guidelines for Regulatory Impact Analysis'' explain in some detail the concept of Quality Adjusted Life Years (QALYs).[249] QALYs, when multiplied by a monetary estimate such as the Value of a Statistical Life Year (VSLY), are estimates of the value that people are willing to pay for life-prolonging and life-improving health care interventions of any kind (see sections 3.2 and 3.3 of the HHS Guidelines for a detailed explanation). The QALY and VSLY amounts used in any estimate of overall benefits are not meant to be precise, but instead are rough statistical measures that allow an overall estimate of benefits expressed in dollars.

Under a common approach to benefit calculation, we can use a Value of a Statistical Life (VSL) to estimate the dollar value of the life-saving benefits of a policy intervention, for a person who more broadly represent a mixture of ages. We use the VSL of approximately $11.5 million in 2021 as described in the HHS Guidelines, adjusted for changes in real income and inflated to 2020 dollars using the Consumer Price Index.[250] Using LTC facilities as an example, and assuming that the average rate of death from COVID–19 (following SARS–CoV–2 infection) at typical LTC facility resident ages and conditions is 5 percent, and the average rate of death after vaccination is essentially zero, the expected value of each resident who would, in the absence of this rule, otherwise be infected with SARS–CoV–2 is about $575,000 ($11.5 million × .05). For staff, who are generally of working ages in roughly the same proportions as the population at large, the typical rate of death for the full course of two vaccines (or possibly three with a booster) is roughly 1 percent of the older adult rate, and the expected value for each employee receiving the same vaccinations is about $57,500 ($11.5 million × .005).[251] For community residents who unvaccinated staff might infect, the resulting calculation is similar (actually somewhat lower because the risk of death from COVID–19 is even lower for those below employment ages).

Under a second approach to benefit calculation, we can estimate the monetized value of extending the life of LTC facility residents, which is based on expectations of life expectancy and the value per life-year. As explained in the HHS Guidelines, the average individual in studies underlying the VSL estimates is approximately 40 years of age, allowing us to calculate a value per life-year of approximately $590,000 and $970,000 for 3 and 7 percent discount rates respectively. This estimate of a value per life-year corresponds to 1 year at perfect health. (These amounts might reasonably be halved for average LTC facility residents, since non-institutionalized U.S. adults aged 80–89 years report average health-related quality of life (HRQL) scores of 0.753, and this figure is likely to be lower for LTC facility residents.[252]) Assuming that the average life expectancy of long term care residents is 5 years, the monetized benefits of saving one statistical life would be about $3.0 million ($590,000 x annually for 5 years) at a 3 percent discount rate and about $4.8 million ($970,000 x annually for 5 years) at a 7 percent discount rate. Assuming that the average rate of death from COVID–19 (SARS–CoV–2 infection) at LTC facility resident ages and conditions is 5 percent, and the average rate of death after vaccination is essentially zero, the expected life-extending value of each resident who would otherwise be infected is $150 thousand at a 3 percent discount rate and $240 thousand at a 7 percent discount rate. A similar calculation can be made for staff and for the community residents they might infect, who will gain many more years of life but whose risk of death is far smaller since their age distribution is so much younger. Deaths from COVID–19 in unvaccinated LTC facility residents during 2020 were about 130,000, or close to one tenth of the average LTC facility resident census of 1.4 million, a huge contrast to the handful of deaths in the vaccination results from Israel.[253] We do not have sufficient data so as to accurately estimate annual resident inflows and outflows over time, but it is clear that over two million new residents and over 700,000 new employees make the total number of individuals involved during the year far higher than point in time or average counts. Moreover, these counts do not include family members and other visitors, whose total visits certainly number in the millions.

Most of the preceding calculations address residential long-term care. Long term care residents are a major group within LTC facilities and are generally in the LTC facility because their needs are more substantial and they need assistance with the activities of daily living, such as cooking, bathing, and dressing. These long-term stays are

[247] The risk of death from infection from an unvaccinated 75- to 84-year-old person is 320 times more likely than the risk for an 18- to 29-years old person. CDC, ''Risk for COVID–19 Infection, Hospitalization, and Death by Age Group'', at *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-age.html.*

[248] We note that as long as most of the world's population remains unvaccinated, another variant of the vaccine might arise and create new risks or shifts in risks within the U.S. That said, the world-wide shortage of vaccines is essentially over taking into account both stocks and existing manufacturing capacity and the biggest problem abroad is getting the available vaccines rapidly into the billions of people who need them.

[249] *https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis.*

[250] We note that the VSL is based on a sample of individuals whose average age is 40, This leads to complexities in estimates for populations who are much younger or older, including LTC residents. See Lisa Robinson and James K. Hammit, ''Valuing Reductions in Fatal Illness Risks: Implications of Recent Research,'' Health Economics, August 2016, pp. 1039–1052.

[251] For the full likelihood distributions for all age ranges, see the CDC age distribution table previously referenced .

[252] Hanmer, J. W.F. Lawrence, J.P. Anderson, R.M. Kaplan, D.G. Fryback. 2006. ''Report of Nationally Representative Values for the Noninstitutionalized US Adult Population for 7 Health-Related Quality-of-Life Scores.'' *Medical Decision Making.* 26(4): 391–400.

[253] Deaths are from COVID–19 Nursing Home Data, CMS, Week Ending 2/21/2021, at *https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/.*

primarily funded by the Medicaid program (also, through long term care insurance or self-financed), and the custodial care services these residents receive are not normally covered by Medicare or any other health insurance.[254] A second major group within the same facilities receives short-term skilled nursing care services. These services are rehabilitative and generally last only days, weeks, or months. They usually follow a hospital stay and are primarily funded by the Medicare program or other health insurance. The importance of these distinctions is that the numbers of residents and typical ages in each category regulated under this rule in each category are different. The average number of persons in facilities for long term care over the course of a year is about 1.2 million residents (as is the point-in-time number), and the total number of persons over the course of a year is about 1.6 million. The average number in skilled nursing care at any one time is about 2 thousand persons, because the average length of stay is weeks rather than years and the median length of stay is days rather than weeks.[255] The annual turnover in this group is such that about 2.3 million residents are served each year. There is some overlap between these two populations and the same person may be admitted on more than one occasion. For purposes of this analysis (these are rough estimates because there are no data routinely published on patient and resident turnover or providing unduplicated counts of persons served), we assume that the expected longevity for each group is identical on average, and that a total of 3.9 million different persons are served each year. The employee staff are a third group and the direct target of these rules. Since both long-term and short-term residents are for the most part served in the same facilities, their care is managed and provided by the same facility staff.

These nursing facilities have about 950,000 full-time equivalent employees at any one time and another 100,000 visiting staff or the equivalent, all covered by this rule. For these persons, the average age is about 45, which creates two offsetting effects: they have more years of life expectancy than residents, but their risk of death from COVID–19 is far lower. For purposes of this analysis, we assume that vaccination against COVID–19 is effective for at least 1 year and use a 1-year period as our primary framework for calculation of potential benefits, not as a specific prediction but as a likely scenario that avoids forecasting major and unexpected changes that are either strongly adverse or strongly beneficial. If we were adding up totals for benefits we would assume that the risk of death after COVID–19 infection is likely only one-half of one percent (one tenth of the resident rate) or less for the unvaccinated members of this group, reflecting the far lower mortality rates for persons who are almost all in the 18 to 65 year old age ranges compared to the far older residents.[256] We assume that the total number of individual employees is 50 percent higher than the full-time equivalent but that only half that number are primarily employed at only one nursing facility, two offsetting assumptions about the number of employees working at each facility (many employees are part-time consultants or the equivalent who serve multiple nursing facilities on a part-time basis). We further assume that employee turnover is 80 percent a year, lower than the results for nurses previously cited. Accordingly, we estimate that 80 percent of 950,000, or 760,000, are new employees each year and must be offered vaccination (again, most are already vaccinated), for a total of 1,710,000 eligible employees over the course of a year. (This number would likely drop in future years as employers decide to hire only persons previously vaccinated and as vaccine uptake increases due to Federal, State, local, or employer requirements, as well as individual choice.)

We have some data on the costs of treating serious illness among the unvaccinated who become infected, are hospitalized, and survive. Among those age 65 years or above, or with severe risk factors, over 30 percent of those known to be infected required hospitalization in the first year of the pandemic.[257] That fraction is far lower now as treatments have improved and as vaccinations have greatly reduced severity of the disease. Among adults aged 21 years to 64 years, about 10 percent of those infected once required hospitalization, but that fraction is now far lower for the same reasons. For our estimates, we assume a 10 percent hospitalization rate among people aged 65 years or older in LTC facilities, reflecting both that their conditions are significantly worse than those of similarly aged adults living independently, and that pre-hospitalization treatments have improved. For staff we assume one fifth of this rate, or 2 percent. Using LTC facilities as our main example, the LTC facility candidates for vaccination in the first year covered by this rule, about three-fourths are age 65 years or above. Hence, the age-weighted hospitalization rate that we project is about 8 percent. Among those hospitalized at any age, the average cost is about $20,000.[258]

To put these cost, benefit, and volume numbers in perspective, vaccinating one hundred previously unvaccinated LTC facility residents who would otherwise become infected with SARS–CoV–2 and have a COVID–19 illness would cost approximately $18,000 ($183 × 100) in vaccination costs. Using the VSL approach to estimation would produce life-saving benefits of about $400,000 for these 100 people ($20,000 × 100 × .05), again assuming the death rate for those ill from COVID–19 of this age and condition is one in twenty. Reductions in health care costs from hospitalization would produce another $160,000 ($20,000 × 100 × .08) in benefits for this group assuming that 8 percent would otherwise be hospitalized. However, this comparison should be taken as necessarily hypothetical and contingent due to the analytic, data, and uncertainty challenges discussed throughout this regulatory impact assessment. Patient benefits are simply a consequence of fewer infections among staff. Vaccinating one hundred previously unvaccinated LTC facility employees would be higher than for staff. Life-saving benefits to employees would be about $5,300,000 ($10,600,000 VSL × 100 × .005) for 100 people assuming that the death rate for these far younger 100 people is 1 in 500 hundred. Reductions in health care costs from hospitalizations of employees would produce another $20,000 ($20,000 × 100 × .01).

[254] For a discussion on this problem, see ''Medicare and You: at *https://www.medicare.gov/medicare-and-you*

[255] In fact, the average length of stay for skilled nursing care is about 25 days. See MEDPAC, Report to the Congress: Medicare Payment Policy, March 2019, ''Skilled nursing facility services,'' page 200.

[256] See the previously cited CDC report on risks by age group. In the age intervals used by CDC, the 40–49-year-old group is in the middle of typical employment age ranges. The risk of death in this age group is one tenth that of those aged 65–74. We emphasize with round numbers that nothing about these data is fixed and unlikely to change (for example, as better future treatments are used to treat severe cases).

[257] The New York Times ''Nearly One-Third of U.S. Coronavirus Deaths Are Linked to Nursing Homes, June 1, 2021.

[258] This is not a robust estimate but is supported by several sources. See for example Jiangzhuo Chen et al, ''Medical costs of keeping the US economy open during COVID–19,'' Scientific Reports, Nature.com, July 19 2020, at *https://pubmed.ncbi.nlm.nih.gov/32743613/,* and Michel Kohli et al, ''The potential public health and economic value of a hypothetical COVID–19 vaccine in the United States: Use of cost-effectiveness modeling to inform vaccination prioritization,'' Science Direct, February 12, 2021, at *https://pubmed.ncbi.nlm.nih.gov/33483216/.*

There remain difficult questions of estimating (1) likely numbers of individuals in staff and patient categories who are likely to be unvaccinated when the rule goes into effect and (2) numbers of staff likely to be willing to accept vaccination in the coming months and years.[259] Both sets of numbers vary substantially by provider and supplier type. LTC facility and home health care patients are on average both the oldest and most health-impaired of those in settings covered by this rule. At the other extreme, rural and other community-care oriented health centers serve the full age spectrum and a lower fraction of severely health-impaired.

We do know that the life-saving benefits for staff are probably small but significant. During the entire period of COVID–19 infections, since March 2020, there have been over 2,000 health care staff deaths recorded by the CDC through October 3, 2021.[260] Of these, the great majority were in the year 2020. Even during the recent Delta variant surge, health care staff deaths decreased to lower levels. Specifically, during the last 6 months, April through September 2021, total staff deaths were 202, an average of 34 per month and no clear trend (the last 4 weeks, all in September, 2021 produced fewer than 20 deaths). This is not surprising as the most effective precautions other than vaccination—masks, social distancing, and ventilation—have been essentially universal in the health care sector during all of 2021. Even more importantly, vaccination rates are considerably higher than in the population at large (although still well below optimal levels). Yet, using the last 6 months of CDC Data Tracker information, on an annual basis more than 400 deaths could be expected. These data, moreover, are almost all among unvaccinated persons and are probably undercounted in current data.

A major caution about these estimates: None of the sources of enrollment information for these programs regularly collect and publish information on client or staff turnover during a year. These data have not previously been found useful in program management for individual agencies or programs, or when needed have been addressed through one-time research projects. The estimates in this analysis are based on inferences from scattered data on average length of stay, mortality, job vacancies, news accounts, and other sources that by happenstance are available for one type of facility or type of resident or another. Nor do we have data on the number of persons in these settings who will be vaccinated through other means during the remainder of the year.

All these data and estimation limitations apply to even the short-term impacts of this rule, and major uncertainties remain as to the future course of the pandemic, including but not limited to vaccine effectiveness in preventing ''breakthrough'' disease transmission from those vaccinated, the long-term effectiveness of vaccination, the emergence of treatment options, and the potential for some new disease variant even more dangerous than Delta.

Another unknown is what currently unvaccinated employees would do when the vaccination deadline is reached, and how rapidly those quitting rather than being vaccinated could be replaced. Even a small fraction of recalcitrant unvaccinated employees could disrupt facility operations. On the other hand, there have been significant reductions in provider and supplier staffing needs in some categories. For example, LTC facility admissions have declined in the last year, as families and caregivers sought to avoid the risks of exposing a care recipient to unvaccinated residents and staff in LTC facilities. The new vaccination requirement may reduce such fears and bring higher numbers of residents to these facilities and the essential services they provide. Again, we have no way to estimate such behavioral changes.

Regardless, we believe it is clear that reductions in patient/resident fatalities through avoiding staff-generated infections are both likely to be a significantly larger benefit from staff vaccination than direct benefits to staff. Staff vaccination will also provide significant community benefits when staff are not at work. Hence, total lives saved under this rule may well reach several hundred a month or perhaps several thousand a month for all three groups in total. Patient and resident benefits are especially likely to be many times higher because the risks of death and serious disease complications are so many times higher among older persons and people with multiple chronic conditions.

As indicated by the preceding analysis, predicting the full range of benefits and costs in either the short run or the next full year with any degree of estimating precision is all but impossible. As the minimum benefit level needed for benefits to exceed costs, however, we estimate that either saving 120 lives, or preventing 600 hundred hospitalizations for serious illness, or any combination of these two magnitudes, would produce benefits that exceed our estimate of costs over the next year. There have been about 200 staff deaths in the last 6 months and this is a likely undercount for this one category of persons alone, and potential life-saving benefits to more than 150 million mostly elderly patients and residents (about 10 percent of whom are likely to remain unvaccinated) who are exposed to provider staff probably would be many times higher. We note, however, as discussed in the preceding section on costs, much of these benefits could be as well attributed to other concurrent and parallel vaccination mandates and campaigns.

E. Other Effects

1. Sources of Payment

The initial costs of this rule fall almost entirely on health care providers and suppliers and are extremely small in comparison to the $4 trillion a year spent on health care, mostly through these same entities. In particular, the costs of the vaccines are paid by the Federal Government and vaccine costs are about two-thirds of the total costs we have estimated. Moreover, through the treatment cost savings to the hospitals and other care providers resulting from the vaccinations that will be made due to this rule, significant savings would accrue to payers. It is likely that half or more of these savings would primarily accrue to Medicare given the age or disability status of most clients and Medicare's role as primary payer, but there would also be substantial savings to Medicaid, private insurance paid by employers and employees, and private out-of-pocket payers including patients and residents. In some rare cases funds under the CARES Act and the American Rescue Plan Act of 2021 might be available at State or local discretion, but it is hard to foresee any substantial budgetary impact on any insurance plan or service provider that would justify or require such assistance.

2. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. Under the RFA, ''small entities'' include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. For

[259] For a survey of the evidence on this issue, see Gillian K. Steelfisher et al, ''An Uncertain Public—Encouraging Acceptance of Covid–19 Vaccines,'' The New England Journal of Medicine, March 3, 2021.

[260] CDC Data Tracker at *https://covid.cdc.gov/covid-data-tracker/#health-care-personnel_healthcare-deaths.*

purposes of the RFA, we estimate that most health care facilities are small entities as that term is used in the RFA because they are either nonprofit organizations or meet the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). HHS uses an increase in costs or decrease in revenues of more than 3 to 5 percent as its measure of ''significant economic impact.'' The HHS standard for ''substantial number'' is 5 percent or more of those that will be significantly impacted, but never fewer than 20.

As estimated previously, the total costs of this rule for 1 year are about $1.3 billion, most of which is directly proportional to number of employees. Spread over 10.4 million full-time equivalent employees, this is about $125 per employee. Assuming a fully loaded average wage per employee of $90,000, the first-year cost does not approach the 3 percent threshold. Moreover, since much of these costs (in particular, the vaccine costs paid by the Federal Government) will not fall on providers or suppliers, the financial strain on these facilities should be negligible. Finally, as previously discussed, there are other concurrent mandates and much of these costs could as well be attributed to those efforts. Therefore, the Department has determined that this IFC will not have a significant economic impact on a substantial number of small entities and that a final RIA is not required. Finally, this IFC was not preceded by a general notice of proposed rulemaking and the RFA requirement for a final regulatory flexibility analysis does not apply to final rules not preceded by a proposed rule. Regardless, this RIA and the main preamble, taken together, would meet the requirements for either an Initial or Final Regulatory Flexibility Analysis.

3. Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare an RIA if a proposed rule may have a significant impact on the operations of a substantial number of small rural hospitals. For purposes of this requirement, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Because this rule has only the small impact per employee calculated for RFA purposes, the Department has determined that this IFC will not have a significant impact on the operations of a substantial number of small rural hospitals. This IFC is also exempt because that provision of law only applies to final rules for which a proposed rule was published. That said, early indications are that rural hospitals are having greater problems with employee vaccination refusals than urban hospitals, and we welcome comments on ways to ameliorate this problem.

4. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates will impose spending costs on State, local, or tribal governments, or by the private sector, require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. This rule contains no State, local, or tribal governmental mandates, but does contain mandates on private sector entities that exceed this amount. However, this IFC was not preceded by a notice of proposed rulemaking, and therefore the requirements of UMRA do not apply. The analysis in this RIA and the preamble as a whole would, however, meet the requirements of UMRA.

5. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule would pre-empt some State laws that prohibit employers from requiring their employees to be vaccinated for COVID–19. Consistent with the Executive Order, we find that State and local laws that forbid employers in the State or locality from imposing vaccine requirements on employees directly conflict with this exercise of our statutory health and safety authority to *require* vaccinations for staff of the providers and suppliers subject to this rule. Similarly, to the extent that State-run facilities that receive Medicare and Medicaid funding are prohibited by State or local law from imposing vaccine mandates on their employees, there is direct conflict between the provisions of this rule (requiring such mandates) and the State or local law (forbidding them). As is relevant here, this IFC preempts the applicability of any State or local law providing for exemptions to the extent such law provides broader grounds for exemptions than provided for by Federal law and are inconsistent with this IFC. In these cases, consistent with the Supremacy Clause of the Constitution, the agency intends that this rule preempts State and local laws to the extent the State and local laws conflict with this rule. The agency has considered other alternatives (for example, relying entirely on measures such as voluntary vaccination, source control alone, and social distancing) and has concluded that the mandate established by this rule is the minimum regulatory action necessary to achieve the objectives of the statute. Given the contagion rates of the existing strains of coronavirus and their disproportionate impacts on Medicare and Medicaid beneficiaries, we believe that vaccination of almost all staff of covered providers and suppliers is necessary to promote and protect patient health and safety. The agency has examined case studies from other employers and concludes that vaccine mandates are vastly more effective than other measures at achieving ideal vaccination rates and the resulting patient protections from morbidity and mortality. Given the emergency situation with respect to the Delta variant detailed more fully above, time did not permit usual consultation procedures with the States, and such consultation would therefore be impracticable. We are, however, inviting State and local comments on the substance as well as legal issues presented by this rule, and on how we can fulfill the statutory requirements for health and safety protections of patients if we were to exempt any providers or suppliers based on State or local opposition to this rule.

F. Alternatives Considered

As discussed earlier in the preamble, a major substantive alternative that we considered was to limit COVID–19 vaccination requirements to full-time employees rather than to all persons who may provide paid or unpaid services, such as visiting specialists or volunteers, who are not on the regular payroll on a weekly or more frequent basis that is, individuals who work in the facility and in some cases infrequently or unpredictably, as well as individuals who are not on the payroll at all. We concluded that covering these persons would be readily manageable without creating major issues for compliance, enforcement, and record-keeping. We did not, however, include some categories of visitors who do not have a business relationship with the provider, such as family member visitors. There are also many issues such as social isolation and loneliness related to potential discouragement of visiting volunteers or family members.

We also considered whether it would be appropriate to limit COVID–19 vaccination requirements to staff who have not previously been infected by SARS–CoV–2. There remain many uncertainties about as to the strength and length of this immunity compared to people who are vaccinated, and—in recognizing that—the CDC recommends that previously infected individuals get vaccinated. Exempting previously infected individuals would have potentially reduced benefits while reducing costs, both roughly in proportion to the number affected. It would have also, complicated administration and likely require standards that do not now exist for reliably measuring the declining levels of antibodies over time in relation to risk of reinfection. Because of current CDC guidance and understanding of relevant scientific findings, we found that it was not warranted to exempt previously infected individuals.

Another option would be to devise a standard with graduated compliance expectations such as 90 percent and then 95 percent and then 100 percent of staff vaccinated and a time period in which to reach each level. A variation of this would be to put providers on a probationary period if they failed to reach 100 percent compliance by the date set in the rule, and were allowed additional time in which to cross that last threshold. Yet another variation would be to reduce payment to providers and suppliers not meeting the standard after the initial deadline. We recently put a phased system in place for Organ Procurement Organizations (OPOs), so we are not reflexively opposed to such options.[261] Nonetheless, there are two major arguments against such a system in the context of this rule. First, to have any usefulness the time periods would have to have a reasonably extensive duration, such as a month each. But that would be almost the same as extending this rule's deadline for an extra several months. We do not believe that extending the deadline to extend the employment of staff who will simply delay vaccination or final refusal to the last possible moment is in the interest of other staff, patients, and patients who would utilize the provider for needed health care if they did not fear unvaccinated staff. Second, it would not only delay the achievement of both staff and patient safety, but encourage procrastination. For those few staff absolutely unwilling to accept vaccination, it would simply delay the day of final action and the day of hiring a vaccinated replacement. In the case of the OPO rule, an entire organization had to be slowly reformed to achieve compliance. In the context of this rule, and the lives at stake, there is no obvious ethical or managerial reason to give a relative handful of vaccination-resisting individuals more time until they leave the organization. It would give management more time to find replacements, but it is not at all clear that this would be a fruitful grace period.

As for a variation reducing payment to non-performing providers, perhaps by 20 percent per patient over some applicable time period, this would arguably provide something better than an ''all of nothing'' removal from provider status. It would require legislation but that is not a barrier to meeting E.O. 12866 analysis standards and in some rules may be essential to a valid benefit-cost analysis. The problem with this variation, however, is that for most providers and suppliers is it unlikely to be a realistic choice. Rather than accept lower payment levels, management can simply terminate the unvaccinated employees, a power they have with or without the reduced payment alternative. Moreover, it would be hard to devise a system that treated equally and fairly providers of all sizes—whether with 5 or 50 employees. We further note that CMS already has and uses discretion in enforcement when inspectors find a violation. Termination of provider status is not normally an immediate consequence, as entities are typically given the opportunity to correct deficiencies. Regardless, we welcome comments on this overall option and its variations, and on the closely-related option of simply adding a month to the compliance deadline in this rule. We considered what standards to apply regarding proof of compliance with exemptions requests base on medical contraindications and religious objections. We decided to establish minimal compliance burdens for both categories of exemptions. This decision on the evidentiary standards could be revisited should an abuse problem arise on a significant scale. This may open the door to forged documents or false statements, and therefore validation of such claims raises administrative costs. Accordingly, we have allowed for relatively relaxed standards for verification in our administrative provisions and cost estimates but may reconsider in the future. We considered alternative timelines for implementation but decided that this would not only delay badly needed live-saving compliance, but also provide little real management benefit to providers and suppliers. Staff have had almost a year to consider COVID–19 vaccinations that are in their own interests as well as vital to patient protections and the protection of other workers. In this regard we note that one of the claimed barriers to vaccination has recently been removed, now that one vaccine is now no longer emergency-authorized, but fully licensed. We believe our requirements provide more than enough time for reasonable counselling and other management measures.

Finally, we considered requiring daily or weekly testing of unvaccinated individuals. We have reviewed scientific evidence on testing and found that vaccination is a more effective infection control measure. As such, we chose not to require such testing for now but welcome comment. Of course, nothing prevents a provider from exercising testing precautions voluntarily in addition to vaccination. We note that nothing in this rule removes the obligation on providers and suppliers to meet existing requirements to prevent the spread of infection, which in practice means that these entities may also conduct regular testing alongside such actions as source control and physical distancing. CMS will continue to review the evidence and stakeholder feedback on this issue.

These and some lesser options are presented and discussed in the main preamble. We do not have reliable dollar estimates for either costs or benefits of any alternatives, for the reasons already discussed in the RIA regarding the options we chose. We welcome comments on these or other options.

G. Accounting Statement and Table

The Accounting Table summarizes the quantified impact of this rule. It covers only 1 year because there will likely be many developments regarding treatments and vaccinations and their effects in future years and we have no way of knowing which will most likely occur. A longer period would be even more speculative than the current estimates. Nonetheless, assuming no major unforeseen events that would impinge on our estimates, we would expect lower costs in future years if for no other reason than increases in the fraction of new hires already vaccinated as well as other positive results from the President's plan or individual vaccination decisions. We further note

[261] See Medicare and Medicaid Programs: Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 FR page 77898, December 2, 2020.

that the vaccinations, and hence the benefits and costs, estimated for this rule are more or less simultaneously being created voluntarily by some employers (self-mandates), through the OSHA vaccination rule applicable to employers of 100 or more persons, and by some State or local mandates. There is no simple and non-arbitrary way to disentangle which vaccination benefits and which vaccination costs are due to which source.

As explained in various places within this RIA and the preamble as a whole, there are major uncertainties as to the effects of current variants of SARS–CoV–2 on future infection rates, medical costs, and prevention of major illness or mortality. For example, the duration of vaccine effectiveness in preventing COVID–19, reducing disease severity, reducing the risk of death, and the effectiveness of the vaccine to prevent disease transmission by those vaccinated are not currently known. These uncertainties also impinge on benefits estimates. For those reasons we have not quantified into annual totals either the life-extending or medical cost-reducing benefits of this rule and have used only a 1-year projection for the cost estimates in our Accounting Statement (our first-year estimates are for the last two months of 2021 and the first ten months of 2022). We also show a large range for the upper and lower bounds of potential costs to emphasize the uncertainty as to several major variables, such as changes in voluntary vaccination levels, longer term effects, and others previously discussed. We welcome comments on all of our assumptions and welcome any additional information that would narrow the ranges of uncertainty or guide us in any important revisions to the requirements established in what is an ''interim'' final rule.

TABLE 8: Accounting Statement—Classification of Estimated Costs and Savings ($millions)

Category	Primary Estimate	Lower Bound	Upper Bound	Units		
				Year Dollars	Discount rate (%)	Period Covered
Benefits: Lives Extended (not annualized or monetized)				2020	7%	2021-2022
Reduced Medical Expenditures (not annualized or monetized)				2020	3%	2021-2022
Benefits Notes: The two largest benefits categories are staff and patient lives extended through vaccinations for COVID-19 and reduced medical costs for vaccinated persons who would otherwise be hospitalized. Patient benefits are larger than staff benefits.						
Costs: Annualized and Monetized ($million/year)	1,380	1040	1730	2020	7%	2021-2022
	1,400	1040	1730	2020	3%	2021-2022
Cost Notes: Administrative costs from increased staff vaccinations.						
Transfers	None					

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 19, 2021.

List of Subjects

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 441

Aged, Family planning, Grant programs—health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Citizenship and naturalization, Civil rights, Health, Health care, Health records, Incorporation by reference, Individuals with disabilities, Medicaid, Medicare, Religious discrimination, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant program—-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

Administrative practice and procedure, Grant programs—health, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 486

Administrative practice and procedure, Grant programs—health, Health facilities, Home infusion therapy, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural and urban areas.

42 CFR Part 494

Diseases, Health facilities, Incorporation by reference, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

■ 1. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Amend § 416.51 by adding paragraph (c) to read as follows:

§ 416.51 Conditions for coverage—Infection control.

* * * * *

(c) *Standard: COVID–19 vaccination of staff.* The ASC must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following center staff, who provide any care, treatment, or other services for the center and/or its patients:

(i) Center employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the center and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following center staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the center setting and who do not have any direct contact with patients and other staff specified in paragraph (c)(1) of this section; and

(ii) Staff who provide support services for the center that are performed exclusively outside of the center setting and who do not have any direct contact with patients and other staff specified in paragraph (c)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (c)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine, prior to staff providing any care, treatment, or other services for the center and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section are fully vaccinated, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (c)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the center has granted, an exemption from the staff COVID–19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized or licensed COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the center's COVID–19 vaccination requirements based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

PART 418—HOSPICE CARE

■ 3. The authority citation for part 418 continues to read as follow:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 4. Amend § 418.60 by adding paragraph (d) to read as follows:

§ 418.60 Condition of participation: Infection control.

* * * * *

(d) *Standard: COVID–19 Vaccination of facility staff.* The hospice must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following hospice staff, who provide any care, treatment, or other services for the hospice and/or its patients:

(i) Hospice employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the hospice and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following hospice staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the settings where hospice services are provided to patients and who do not have any direct contact with patients, patient families and caregivers, and other staff specified in paragraph (d)(1) of this section; and

(ii) Staff who provide support services for the hospice that are performed exclusively outside of the settings where hospice services are provided to patients and who do not have any direct contact with patients, patient families and caregivers, and other staff specified in paragraph (d)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the hospice and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (d)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the hospice has granted, an exemption from the staff COVID–19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the hospice's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

■ 5. The authority citation for part 441 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 6. Amend § 441.151 by adding paragraph (c) to read as follows:

§ 441.151 General requirements.

* * * * *

(c) *COVID–19 Vaccination of facility staff.* The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or resident contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its residents:

(i) Facility employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with residents and other staff specified in paragraph (c)(1) of this section; and

(ii) Staff who provide support services for the facility that are performed exclusively outside of the center setting and who do not have any direct contact with residents and other staff specified in paragraph (c)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (c)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its residents;

(ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been

granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring that the facility follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID–19, and which must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (c)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID–19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 7. The authority citation for part 460 continues to read as follow:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

■ 8. Amend § 460.74 by adding paragraph (d) to read as follows:

§ 460.74 Infection control.

* * * * *

(d) *COVID–19 Vaccination of PACE organization staff.* The PACE organization must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or participant contact, the policies and procedures must apply to the following PACE organization staff, who provide any care, treatment, or other services for the PACE organization and/or its participants:

(i) PACE organization employees;

(ii) Licensed practitioners providing services on behalf of the PACE organization;

(iii) Students, trainees, and volunteers providing services on behalf of the PACE organization; and

(iv) Individuals who provide care, treatment, or other services on behalf of the PACE organization, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following PACE organization staff:

(i) Staff who exclusively provide telehealth or telemedicine services for the PACE organization and/or its participants and who do not have any direct contact with participants and other PACE organization staff specified in paragraph (d)(1) of this section; and

(ii) Staff who provide support services for the PACE organization and/or its participants and who do not have any direct contact with participants and other PACE organization staff specified in paragraph (d)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the PACE organization and/or its participants;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (d)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the PACE organization has granted, an exemption from the staff COVID–19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as

defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the PACE organization's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 9. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

■ 10. Amend § 482.42 by adding paragraph (g) to read as follows:

§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(g) *Standard: COVID–19 Vaccination of hospital staff.* The hospital must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following hospital staff, who provide any care, treatment, or other services for the hospital and/or its patients:

(i) Hospital employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the hospital and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following hospital staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the hospital setting and who do not have any direct contact with patients and other staff specified in paragraph (g)(1) of this section; and

(ii) Staff who provide support services for the hospital that are performed exclusively outside of the hospital setting and who do not have any direct contact with patients and other staff specified in paragraph (g)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (g)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the hospital and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (g)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (g)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the hospital has granted, an exemption from the staff COVID–19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the hospital's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 11. The authority citation for part 483 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r.

■ 12. Amend § 483.80 by revising paragraph (d)(3)(v) and adding paragraph (i) to read as follows:

§ 483.80 Infection control.

(d) * * *

(3) * * *

(v) The resident or resident representative, has the opportunity to accept or refuse a COVID–19 vaccine, and change their decision; and

* * * * *

(i) *COVID–19 Vaccination of facility staff.* The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or resident contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its residents:

(i) Facility employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with residents and other staff specified in paragraph (i)(1) of this section; and

(ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with residents and other staff specified in paragraph (i)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (i)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its residents;

(ii) A process for ensuring that all staff specified in paragraph (i)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (i)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID–19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

■ 13. Amend § 483.430 by revising paragraph (f) to read as follows:

§ 483.430 Condition of participation: Facility staffing.

* * * * *

(f) *Standard: COVID–19 Vaccination of facility staff.* The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or client contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its clients:

(i) Facility employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the facility and/or its clients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with clients and other staff specified in paragraph (f)(1) of this section; and

(ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with clients and other staff specified in paragraph (f)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (f)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care,

treatment, or other services for the facility and/or its clients;

(ii) A process for ensuring that all staff specified in paragraph (f)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (f)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID–19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

■ 14. Amend § 483.460 by revising paragraph (a)(4)(v) to read as follows:

§ 483.460 Condition of participation: Health care services.

* * * * *

(a) * * *

(4) * * *

(v) The client, or client's representative, has the opportunity to accept or refuse a COVID–19 vaccine, and change their decision;

* * * * *

PART 484—HOME HEALTH SERVICES

■ 15. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 16. Amend § 484.70 by adding paragraph (d) to read as follows:

§ 484.70 Condition of participation: Infection prevention and control.

* * * * *

(d) *Standard: COVID–19 Vaccination of Home Health Agency staff.* The home health agency (HHA) must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following HHA staff, who provide any care, treatment, or other services for the HHA and/or its patients:

(i) HHA employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the HHA and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following HHA staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the settings where home health services are directly provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (d)(1) of this section; and

(ii) Staff who provide support services for the HHA that are performed exclusively outside of the settings where home health services are directly provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (d)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the HHA and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (d)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the HHA has granted, an exemption from the staff COVID–19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the HHA's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 17. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395(hh).

■ 18. Amend § 485.58 by revising paragraph (d)(4) to read as follows:

§ 485.58 Condition of participation: Comprehensive rehabilitation program.

* * * * *

(d) * * *

(4) The services must be furnished by personnel that meet the qualifications of § 485.70 and the number of qualified personnel must be adequate for the volume and diversity of services offered. Personnel that do not meet the qualifications specified in § 485.70(a) through (m) may be used by the facility in assisting qualified staff. When a qualified individual is assisted by these personnel, the qualified individual must be on the premises, and must instruct these personnel in appropriate patient care service techniques and retain responsibility for their activities.

* * * * *

■ 19. Amend § 485.70 by adding paragraph (n) to read as follows:

§ 485.70 Personnel qualifications.

* * * * *

(n) The CORF must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its patients:

(i) Facility employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (n)(1) of this section; and

(ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (n)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (n)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (n)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (n)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID–19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions

and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

■ 20. Amend § 485.640 by adding paragraph (f) to read as follows:

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(f) *Standard: COVID–19 Vaccination of CAH staff.* The CAH must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following CAH staff, who provide any care, treatment, or other services for the CAH and/or its patients:

(i) CAH employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the CAH and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following CAH staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the CAH setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section; and

(ii) Staff who provide support services for the CAH that are performed exclusively outside of the CAH setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (f)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the CAH and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (f)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (f)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the CAH has granted, an exemption from the staff COVID–19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the CAH's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

■ 21. Amend § 485.725 by adding paragraph (f) to read as follows:

§ 485.725 Condition of participation: Infection control.

* * * * *

(f) *Standard: COVID–19 vaccination of organization staff.* The organization that provides outpatient physical therapy must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following organization staff, who provide any care, treatment, or other services for the organization and/or its patients:

(i) Organization employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the organization and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following organization staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the organization setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section; and

(ii) Staff who provide support services for the organization that are performed exclusively outside of the organization setting and who do not have any direct contact with patients and other staff

specified in paragraph (f)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (f)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the organization and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (f)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status for all staff specified in paragraph (f)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the organization has granted, an exemption from the staff COVID–19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the organization's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

■ 22. Amend § 485.904 by adding paragraph (c) to read as follows:

§ 485.904 Condition of participation: Personnel qualifications.

* * * * *

(c) *Standard: COVID–19 vaccination of center staff.* The CMHC must develop and implement policies and procedures to ensure that all center staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or client contact, the policies and procedures must apply to the following center staff, who provide any care, treatment, or other services for the center and/or its clients:

(i) Center employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the center and/or its clients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following center staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the center setting and who do not have any direct contact with clients and other staff specified in paragraph (c)(1) of this section; and

(ii) Staff who provide support services for the center that are performed exclusively outside of the center setting and who do not have any direct contact with clients and other staff specified in paragraph (c)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (c)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the CMHC and/or its clients;

(ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status for all staff specified in paragraph (c)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the CMHC has granted, an exemption from the staff COVID–19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions

from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the CMHC's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 23. The authority citation for part 486 continues to read as follows:

Authority: 42 U.S.C. 273, 1302, 1320b–8, and 1395hh.

■ 24. Amend § 486.525 by adding paragraph (c) to read as follows:

§ 486.525 Required services.

* * * * *

(c) *COVID–19 Vaccination of facility staff.* The qualified home infusion therapy supplier must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following qualified home infusion therapy supplier staff, who provide any care, treatment, or other services for the qualified home infusion therapy supplier and/or its patients:

(i) Qualified home infusion therapy supplier employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the qualified home infusion therapy supplier and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following qualified home infusion therapy supplier staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the settings where home infusion therapy services are provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (c)(1) of this section; and

(ii) Staff who provide support services for the qualified home infusion therapy supplier that are performed exclusively outside of the settings where home infusion therapy services are provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (c)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (c)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the qualified home infusion therapy supplier and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring that the facility follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID–19, and which must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status for all staff specified in paragraph (c)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the qualified home infusion therapy supplier has granted, an exemption from the staff COVID–19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains;

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the qualified home infusion therapy supplier's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

■ 25. The authority citation for part 491 continues to read as follows:

Authority: 42 U.S.C. 263a and 1302.

■ 26. Amend § 491.8 by adding paragraph (d) to read as follows:

§ 491.8 Staffing and staff responsibilities.

* * * * *

(d) *COVID–19 vaccination of staff.* The RHC/FQHC must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following clinic or center staff, who provide any care, treatment, or other services for the clinic or center and/or its patients:

(i) RHC/FQHC employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the clinic or center and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following clinic or center staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the clinic or center setting and who do not have any direct contact with patients and other staff specified in paragraph (d)(1) of this section; and

(ii) Staff who provide support services for the clinic or center that are performed exclusively outside of the clinic or center setting and who do not have any direct contact with patients and other staff specified in paragraph (d)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the clinic or center and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring that the clinic or center follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID–19, and which must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status for all staff specified in paragraph (d)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID–19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains;

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the clinic's or center's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

■ 27. The authority citation for part 494 continues to read as follows:

Authority: 42 U.S.C. l302 and l395hh.

■ 28. Amend § 494.30 by—

■ a. Redesignating paragraphs (b) and (c) as paragraphs (c) and (d) respectively, and

■ b. Adding a new paragraph (b).

The addition reads as follows:

§ 494.30 Condition: Infection control.

* * * * *

(b) *COVID–19 Vaccination of facility staff.* The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its patients:

(i) Facility employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with

patients and other staff specified in paragraph (b)(1) of this section; and

(ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (b)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (b)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (b)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status for all staff specified in paragraph (b)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID–19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

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Part III

Department of Justice

Larry C. Daniels, M.D.; Decision and Order; Notice

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 19–33]

Larry C. Daniels, M.D.; Decision and Order

On June 21, 2019, a former Assistant Administrator of Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Larry C. Daniels M.D., (hereinafter, Respondent or Dr. Daniels) of Shreveport, Louisiana. Administrative Law Judge Exhibit (ALJ–– 1, (OSC) at 1. The OSC proposed to deny his pending application No. W18024499C for a DEA Certificate of Registration (hereinafter, COR or registration) pursuant to 21 U.S.C. 823(f) and 824(a)(1) for the reason that Respondent's ''registration would be inconsistent with the public interest,'' and because he ''materially falsified [his] application for registration.'' *Id.*

In response to the OSC, Respondent requested a hearing before an Administrative Law Judge. ALJ–2. The hearing in this matter was held in Shreveport, Louisiana on November 13–15, 2019. On January 24, 2020, Administrative Law Judge Charles Wm. Dorman (hereinafter, the ALJ) issued Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD), and on February 11, 2020, the Respondent filed exceptions (hereinafter, Resp Exceptions) to the Recommended Decision. The Government filed exceptions (hereinafter, Govt Exceptions) to the Recommended Decision on February 13, 2020. I address the Government's Exceptions, which were limited to the material falsification allegations, in the RD at Section Analysis.III. I address the Respondent's Exceptions, which were focused on the ALJ's finding that Dr. Daniels had not accepted responsibility and his recommended sanction, in the Sanction Section, and I issue the final order in this case following the RD. The ALJ transmitted the record to me on February 19, 2020. Having reviewed the entire record, I adopt the ALJ's rulings, findings of fact, as modified, conclusions of law and recommended sanction with minor modifications, where noted herein.[*A]

[*A] I have made minor modifications to the RD. I have substituted initials or titles for the names of witnesses and patients to protect their privacy and I have made minor, nonsubstantive, grammatical changes and nonsubstantive, conforming edits. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have noted the edits with an asterisk, and I have included specific descriptions of the modifications in brackets following the asterisk or in footnotes marked with a letter and an asterisk. Within those brackets and footnotes, the use of the personal pronoun ''I'' refers to myself—the Administrator.

Joshua H. Packman, Esq. and David M. Locher, Esq. for the Government
Sam L. Jenkins, Jr., Esq. for the Respondent

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision

[*B] The issue before the Administrator is whether the record as a whole establishes b a preponderance of the evidence thatg the DEA should den the application for a Certificate of Registration of Larr C. Daniels, M.D., Application Number W18024499C, pursuant to 21 UJ.SC. §§ 823(f) and 824(a)(1) and (a)(4), because he materiall falsified his application and because granting him a registration would be inconsistent with the public interest. ALJ–7.

In issuing this Recommended Decision, I have considered the entire Administrative Record, including all of the testimony, admitted exhibits, and the oral and written arguments of counsel.

The Allegations

Material Falsification

1. On March 12, 2018, the Louisiana State Board of Medical Examiners (''the Board'') issued a Consent Order that ''imposed a continuing restriction on [Dr. Daniels'] ability to practice medicine and to prescribe controlled substances for pain management or addiction treatment.'' ALJ–1, at 3–4, para. 8(c). Dr. Daniels' application for a DEA certificate of registration, dated March 16, 2018, failed to disclose the restriction imposed by the Board's Consent Order on his Louisiana state controlled substance license. *Id.* at 3–4, paras. 8–9. Dr. Daniels' failure to disclose the restriction imposed by the Board's Consent Order on his state controlled substance license constitutes a material falsification of his application for DEA registration, in violation of 21 U.S.C. 824(a)(1). *Id.*

Addiction Treatment

2. Between May 2016 and September 2017, Dr. Daniels prescribed controlled substances to patients AK, CA, MN, JD, SB, and CM. ALJ–1, at 4, paras. 10–12. Dr. Daniels' prescriptions for controlled substances to these patients exhibited the following deficiencies:

a. Dr. Daniels failed to conduct a physical examination of any of these patients;

b. Dr. Daniels failed to request these patients' medical records concerning prior substance abuse or past treatment of substance abuse;

c. Dr. Daniels failed to obtain a report from the Louisiana Prescription Monitoring Program for any of these patients;

d. Dr. Daniels failed to address in these patients' medical records the results of abnormal urine drug screens, to include results that were positive for illicit substances and negative for substances that Dr. Daniels prescribed;

e. Dr. Daniels failed to document in these patients' medical records his rationale for his medical treatment of these patients, to include his reason for initiating buprenorphine treatment at high dosages. ALJ–1, at 5, para. 12(a)-(e).

3. In addition, Dr. Daniels issued to patients AK, CA, MN, SB, and CM, prescriptions for both buprenorphine (Subutex) and clonazepam. ALJ–1, at 5, para. 13. Prescribing these controlled substances to a patient at the same time can pose potential risks for that patient. *Id.* Dr. Daniels failed to document in the patients' medical records any rationale that justified prescribing buprenorphine and clonazepam at the same time. *Id.* Dr. Daniels also failed to document in the patients' medical records that he discussed with them the risks of taking these controlled substances at the same time. *Id.* Specifically, Dr. Daniels issued the following prescriptions in violation of state and federal law:

a. Between January 2017 and August 2017, Dr. Daniels prescribed AK buprenorphine (Subutex) on nine occasions and clonazepam (Klonopin) on at least eight of those occasions. ALJ–1, at 5, para. 14(a).

b. Between June 2016 and September 2017, Dr. Daniels prescribed CA buprenorphine (Subutex) and clonazepam (Klonopin) on at least 19 occasions, an amphetamine-dextroamphetamine mixture (Adderall) on 18 of those occasions. *Id.* at 6, para. 14(b). Dr. Daniels failed to document in CA's medical record any rationale for prescribing Adderall to CA. *Id.* at 6, para. 14(b)(i).

c. Between May 2017 and August 2017, Dr. Daniels prescribed MN buprenorphine (Subutex) and clonazepam (Klonopin) on at least five occasions. *Id.* at 6, para. 14(c).

d. Between August 2016 and August 2017, Dr. Daniels prescribed JD buprenorphine (Subutex) on at least 15 occasions. *Id.* at 6, para. 14(d).

e. Between January 2017 and July 2017, Dr. Daniels prescribed SB

[*B] I have submitted the RD's discussion of the procedural histor to avoid repetition with m introduction.

buprenorphine (Subutex) and clonazepam (Klonopin) on at least seven occasions. *Id.* at 6, para. 14(e).

f. Between May 2016 and September 2017, Dr. Daniels prescribed CM buprenorphine (Subutex) on at least 18 occasions and clonazepam (Klonopin) on 10 of those occasions. *Id.* at 6, para. 14(f).

4. For the reasons listed in Allegations 2 and 3, the prescriptions that Dr. Daniels issued to AK, CA, MN, JD, SB, and CM, were beneath the standard of care for the practice of medicine in Louisiana, outside the usual course of professional practice, and not for a legitimate medical purpose, in violation of 21 U.S.C. 841(a), 842(a); 21 CFR 1306.04(a); La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1); La. Admin. Code tit. 46, Pt. XLV, §§ 6919, 6921; and La. Admin. Code tit. 48, Pt. I, §§ 5637, 5647, 5723, 5725, 5731. ALJ–1, at 4–6, paras. 10–15.

Pain Management

5. Dr. Daniels issued controlled substance prescriptions for pain management to JW that exhibited the following deficiencies:

a. Dr. Daniels' records for follow-up visits with JW lack any indicia of a meaningful doctor-patient relationship, because the physical examination records for JW are incomplete, cursory, non-diagnostic, non-contributory, and/or lack notations of vital signs. ALJ–1, at 6, para. 16(a).

b. Dr. Daniels duplicated the therapeutic effect of the opioids he prescribed to JW by prescribing JW oxycodone-acetaminophen (Percocet), oxycodone extended release (OxyContin), and hydrocodone-acetaminophen (Lortab), after initially prescribing him methadone. *Id.* at 6, para. 16(b). Therapeutic duplication increases the risk of unintentional overdose. *Id.*

c. Between March 2014 and January 2017, Dr. Daniels prescribed JW OxyContin and methadone at the same time. *Id.* at 7, para. 16(c). In July 2014, Dr. Daniels prescribed JW Percocet and Lortab at the same time. *Id.* Dr. Daniels failed to document in JW's medical records any justification for these prescriptions. *Id.* at 7, para. 16(d).

d. In addition, Dr. Daniels failed to document in JW's medical records any justification for increasing JW's monthly methadone prescription in January 2016 from 150 units of methadone 10 mg to 180 units. *Id.* at 7, para. 16(d).

e. Between August 2013 and April 2017, Dr. Daniels issued to JW at least 56 prescriptions for Percocet; 7 prescriptions for OxyContin (5 at the same time as Percocet); and 1 prescription for Lortab. ALJ–1, at 7, para. 17.

f. Between January 2016 and March 2017, Dr. Daniels issued to JW at least 15 prescriptions for methadone at the increased dosage of 180 units, 5 at the same time as prescriptions for Percocet. *Id.* at 7, para. 17.

6. For the reasons listed in Allegation 5, the prescriptions that Dr. Daniels issued to JW were beneath the standard of care for the practice of medicine in Louisiana, outside the usual course of professional practice, and not for a legitimate medical purpose, in violation of 21 U.S.C. 841(a), 842(a); 21 CFR 1306.04(a); La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1); and La. Admin. Code tit. 46, Pt. XLV, §§ 6919, 6921. ALJ–1, at 6–7, paras. 16–17.

Undercover Officer (''TC'')

7. On September 13, 2017, Dr. Daniels prescribed 60 units of Suboxone (buprenorphine/naloxone) 8/2 mg to TC. ALJ–1, at 7, para. 18. Among other issues, this prescription exhibited the following deficiencies:

a. Dr. Daniels failed to conduct a physical examination of TC;

b. Dr. Daniels failed to request any medical records of TC's prior substance abuse or past treatment for substance abuse;

c. Dr. Daniels failed to obtain a *[Prescription Monitoring Program (hereinafter,] PMP) report for TC. *Id.* at 7, para. 19.

8. Furthermore, Dr. Daniels initiated Suboxone treatment for TC at 16/4 mg per day despite TC's negative urine drug screen; TC's report to Dr. Daniels that he had not taken any opioids for two-to-three weeks; and Dr. Daniels' recognition that TC's presentment of addiction was not severe. ALJ–1, at 8, para. 19.

9. Dr. Daniels' medical records for TC fail to provide adequate information about Dr. Daniels' evaluation and treatment plan for TC, and are so cursory that they lack credibility. ALJ–1, at 8, para. 19.

10. For the reasons listed in Allegations 7–9, the prescription that Dr. Daniels issued to TC was beneath the standard of care for the practice of medicine in Louisiana and outside the usual course of professional practice, in violation of 21 U.S.C. 841(a) and 842(a); 21 CFR 1306.04(a); and La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1). ALJ–1, at 8, para. 19.

Witnesses

I. The Government's Witnesses

The Government presented its case through the testimony of three witnesses. The Government first presented the testimony of a Diversion Investigator (''the DI''). Tr. 25–72. The DI also testified as a rebuttal witness. Tr. 588–99.

This witness has been a Diversion Investigator for 11 years. Tr. 26. She briefly testified concerning her work history with the DEA and her training. Tr. 26–28. The DI became familiar with Dr. Daniels after the Shreveport Resident Office of the DEA received information that Dr. Daniels was prescribing excessive amounts of controlled substances. Tr. 28.

The DI reviewed the Consent Order (''the Order'') issued to Dr. Daniels by the Louisiana State Board of Medical Examiners (''the Board''), highlighting restrictions placed on Dr. Daniels' ability to practice medicine by that Order. Tr. 33–34. The DI then reviewed Dr. Daniels' application for a DEA Certificate of Registration, noting that he had provided affirmative answers to two of the liability questions on the application. Tr. 38–39. The DI testified that had Dr. Daniels provided information that was more consistent with the content of the Order, that that information would have been relevant in assisting the DEA when making a decision about what action to take on Dr. Daniels' application. Tr. 39–41. *[The DI stated that the Order was ''ambiguous'' and that ''it's a requirement for the registrant to notify DEA that he has specific restrictions as in reference to controlled substances.'' Tr. 65; *see also* Tr. 72.] *[The DI testified that] the application itself, however, does not inform an applicant to provide the *[incident result] information that the DI asserted was missing from Dr. Daniels' application, which *[DEA alleged] constituted a material misrepresentation. [Tr. 70]. The information Dr. Daniels provided on his application, however, placed the DEA on notice that it should not summarily approve Dr. Daniels' application, but rather DEA should investigate it. Tr. 71.

Testifying as a rebuttal witness, the DI identified Government Exhibit 29 as a subpoena issued to the Louisiana Board of Pharmacy's Prescription Monitoring Program. Tr. 590. She also identified Government Exhibit 30 as the response to Government Exhibit 29. Tr. 593. In response to the subpoena, the Board of Pharmacy produced a 20-page history of Dr. Daniels' logins to the Louisiana PMP from June 2, 2016, through September 9, 2019. Tr. 593, 599. The history showed that Dr. Daniels had queried the PMP with respect to only two of the named patients in the OSC, patients TC and CA. Tr. 597. Both inquiries were made on September 13, 2017. Tr. 598.

During the Government's case-in-chief, and as a rebuttal witness, the DI presented her testimony in a professional, clear, and concise manner, and her demeanor was appropriate. Accordingly, I fully credit her testimony.

The Government's second witness was Task Force Officer (''TC''), a detective with the DeSoto Parish Sheriff's Office. Tr. 73–104. TC provided a brief overview of his law enforcement training. Tr. 74–76. He became aware of Dr. Daniels during undercover operations, in which he went to the doctor's office. Tr. 76. TC went to Dr. Daniels' office twice in September 2017, and made audio and video recordings during each visit. Tr. 76–77, 80; GE–24, 27. TC testified that Government Exhibit 24 is a complete and accurate recording of his visit with Dr. Daniels on September 13, 2017. Tr. 85.

TC detailed what happened during his visit to the clinic on September 12, 2017. Tr. 77–80. During that visit, TC provided a urine sample, his vitals were taken, and he talked with a counselor. *Id.* The details of what he told the counselor are documented in the counselor's notes. Tr. 87; GE–23, at 2–6. TC's urine screen was negative. Tr. 89; GE–23, at 9.

TC also detailed what happened when he returned to the clinic on September 13, 2017. Tr. 80–85. During that visit, he informed Dr. Daniels of his prior use of Lortab, Percocet, Adderall, and Suboxone, which he obtained ''off the street.'' Tr. 82–84. He also told Dr. Daniels that he drank alcohol. Tr. 82. Dr. Daniels did not caution TC about combining medications with each other or with alcohol and he did not physically examine TC. Tr. 82–84; GE–25. TC left the appointment with a prescription for Suboxone that Dr. Daniels issued to him. Tr. 85; GE–23, at 1.

TC presented his testimony in a professional, clear, and concise manner. In addition, his testimony was consistent with other evidence of record. Accordingly, I credit his testimony.

The third witness called by the Government was its expert, Dr. Gene Kennedy, M.D. He testified during the Government's case-in-chief, Tr. 106–416, and as a rebuttal witness. Tr. 600–04.

Dr. Kennedy currently maintains his own pain practice, Island Pain Care, on St. Simon's Island, Georgia. Tr. 107. He detailed his education, training, and professional experience. Tr. 107–111. Dr. Kennedy graduated from LSU with a degree in biology. Tr. 107. He obtained his medical degree from New York Medical College, and he then did a residency in family medicine in Wheeling, West Virginia, and then practiced family medicine in Ohio for many years. *Id.* In 2000, Dr. Kennedy relocated to Georgia. Tr. 109. Dr. Kennedy has been involved in pain management since his residency because a lot of family practice deals with pain management. *Id.* Dr. Kennedy opened his pain management clinic in 2004–05. Dr. Kennedy also treats patients who have substance abuse disorders, and he prescribes Suboxone to them. Tr. 109–10. Dr. Kennedy has a DEA Certificate of Registration, which includes an ''X'' number. Tr. 111. Dr. Kennedy identified Government Exhibit 26 as his resume. Tr. 111–12. Dr. Kennedy lectures on the differences between legitimate and illegitimate prescribing of controlled substances. Tr. 114–15. He has also testified as an expert witness at administrative hearings, and in both civil and criminal cases. Tr. 115. Dr. Kennedy testified that the standard of care that a doctor needs to meet is, for the most part, standard across the country, recognizing that individual states may have individual requirements. Tr. 119–34. *[He further testified that ''there are individual variations with states, and understanding that nobody's medical records are perfect then you analyze the chart and apply the regulations as best you reasonably can when doing a review.'' Tr. 120.]

There being no objection [*C] raised by Dr. Daniels, I accepted Dr. Kennedy as an expert in the areas of addiction treatment, pain management, and the standard of care for prescribing controlled substances for addiction treatment, and for pain management in the State of Louisiana. Tr. 134, 140.

Dr. Kennedy testified that the standard of care for prescribing controlled substances for the treatment of chemical dependency requires: An adequate physical examination; obtaining a medical history and past medical records; obtaining PMP reports; conducting drug screening; and maintaining complete and accurate medical records. Tr. 141–51. Dr. Kennedy recognized that no doctor can document everything that occurs during a patient encounter, but the doctor should document the important, pertinent information such that it will give a picture of what happened during the encounter to an objective reviewer of those records. Tr. 151–52. Dr. Kennedy also acknowledged that a reviewer of medical records must keep an open mind, and, at times, afford the treating doctor the benefit of the doubt. Tr. 153, 294, 296–98, 336.

In preparation for his testimony, Dr. Kennedy reviewed the medical records and the PMP reports of the patients identified in the Order to Show Cause. Tr. 159. In rendering his opinions concerning the prescriptions he reviewed, Dr. Kennedy noted that ''rarely is [his opinion] based on a single thing,'' rather it is developed after reviewing medical records and ''[i]t reaches a point where . . . it's simply not possible to say that what I'm looking at is credible medical care.'' Tr. 195. Dr. Kennedy further noted that accidents do happen in medical records, ''but when you have a repetitive pattern of medical records missing critical information, it's not excusable.'' Tr. 295. With respect to treatment plans, Dr. Kennedy testified that he does not criticize a treatment plan ''as long as I can determine that there is a rationale behind it.'' Tr. 298.

Dr. Kennedy proceeded to review the patient files contained in this case, and rendered his opinion that most of the prescriptions identified in the Order to Show Cause, written by Dr. Daniels, were issued outside the usual or acceptable course of professional medical practice and were not issued for legitimate medical purposes. Tr. 191–92, 206, 220, 231, 238, 244, 255, 261, 266, 278–83, 372–73. As a rebuttal witness, Dr. Kennedy slightly modified his testimony concerning Dr. Daniels' treatment of patient TC. Tr. 601–04. While Dr. Kennedy's opinion had not changed as to whether the prescription that Dr. Daniels issued to TC was outside the standard of care, and outside the usual course of professional practice, Tr. 602–03, he testified that Dr. Daniels may have believed he had a legitimate medical purpose to issue the prescription. Tr. 602. Concerning the question of ''whether or not it was issued for a legitimate medical purpose,'' Dr. Kennedy testified that he ''would have to go over everything again to make a final decision . . . .'' Tr. 602.[*D]

[*C] Despite not raising objections at the hearing, Dr. Daniels suggests in his posthearing brief that Dr. Kennedy's testimony should be considered in light of the fact that he ''has never practiced medicine in the State of Louisiana.'' Respondent's Posthearing, at 4. In this case, I find that Dr. Kennedy primarily relied on Louisiana law and regulations to formulate his opinion regarding the standard of care and usual course of professional practice and the laws provide extremely strong support for his testimony. *See infra* Analysis.V.

[*D] Ultimately, I find that the distinction that Dr. Kennedy makes here with regard to whether the prescription had a legitimate medical purpose is not entirely relevant considering Louisiana law and the CSA regulations. As explained below, Louisiana law mirrors the DEA regulations in providing that ''[a]n order purporting to be a prescription issued

Dr. Kennedy presented his testimony in a professional, candid, and straightforward manner. He also presented his testimony in an objective manner, and as a witness who had no stake in the outcome of the case. In addition, the testimony of Dr. Kennedy was sufficiently detailed, plausible, and internally consistent. Furthermore, Dr. Kennedy's testimony went unrebutted.[1] Therefore, I merit it as fully credible in this Recommended Decision.

II. Respondent's Witnesses

Respondent presented his case through the testimony of two witnesses. The Respondent's first witness was LW (''LW''). Tr. 418–69. LW was the owner of the Medical Clinic (''the Clinic'') where Dr. Daniels worked. Tr. 419. The Clinic closed on October 3, 2017. *Id.* While in operation, the Clinic provided services for patients who had low, to mid-level incomes, and who were being treated for some kind of opioid addiction. Tr. 421–22. Between January 2016 and April 24, 2017, LW was at the Clinic one evening a week. *Id.* On April 24, 2017, LW started working at the Clinic full time and oversaw its day-to-day operations. Tr. 420. LW is a medical assistant. Tr. 445.

LW provided testimony about how the Clinic operated after April 24, 2017. Tr. 430–31. After that date, Dr. Daniels worked at the Clinic just one evening a week and saw about 25 patients a week. Tr. 424–25. He was the only doctor who worked at the Clinic. Tr. 427. In addition to Dr. Daniels and LW, the Clinic employed five other individuals. Tr. 425–26. LW testified about the duties of those employees. Tr. 428–29, 431–34, 436–41. Each of the employees played a part in assembling the patients' medical records. Tr. 427, 438. LW testified that each new patient submitted to a urine drug screen and that the Clinic checked the patient's PMP. Tr. 442–43, 446. Information about the results of the drug screening and the PMP were provided to Dr. Daniels. Tr. 443. Although LW testified that after she started working at the Clinic full-time, Clinic employees always checked the PMP, she did not know if that information was placed into a patient's medical record. Tr. 448.

In general, I found LW to be a sincere and credible witness who testified about how she thought the Clinic was running after she took over the day-to-day operations. It was also obvious that she has a sincere interest in providing health services to an underserved community. For someone who was overseeing the day-to-day operations of the Clinic, however, her testimony was less than clear about when and how PMPs were run, and how the results of the PMP search and of the urine drug screens were provided to Dr. Daniels. Although she testified that the PMP report was run for each patient, Tr. 442, it was not clear when the clinic ran PMP's on patients. She testified it was run when the patient came in, and it was run after they saw the social worker, ''it was run constantly.'' Tr. 457–59. Further, LW was not clear on what information from the PMP was shared with Dr. Daniels. Tr. 460–465. In that her testimony about running PMP reports on every patient is directly contradicted by Government Exhibit 30,[2] I give little weight to this testimony. Further, while LW testified that urine drug screens were taken for each patient, Tr. 443, she also testified that the Clinic discovered that the results of those tests were not always in the patients' charts. Tr. 427, 439. I find that LW's testimony about having patients submit to urine drug screening is generally consistent with other evidence of record, namely the large number of drug screening reports that are in the patients' medical records. Thus, with the exception of LW's testimony about PMPs, I give credit to LW's testimony.

Next, Dr. Larry Daniels, M.D., testified on his own behalf. Tr. 475–586. Dr. Daniels worked at the Shreveport Job Corps Center, the Diabetes Management Center, and the Clinic. Tr. 475. Dr. Daniels has practiced medicine in Louisiana since 1983. Tr. 476. He practiced for one year in Houston, Texas, from 1999 to 2000. Tr. 476–77. Dr. Daniels received compensation for his services at the Clinic from the Clinic itself, and not from patients. Tr. 480. Throughout his career, Dr. Daniels has worked for multiple clinics that provide medical services to low-income patients, and he has treated patients who had chemical dependencies. Tr. 482–84. Dr. Daniels worked at the Clinic on Wednesday evenings. Tr. 488. He would normally see about 10–20 patients on those evenings. *Id.*

The Clinic was located in Minden, Louisiana, which is a rural area. Tr. 480. Dr. Daniels worked at the David Raines Community Health Center (''Community Health Center'') at the same time that he worked at the Clinic. *Id.* Before working at the Clinic, Dr. Daniels had experience in private practice and at the Community Health Center in treating chemical dependency. Tr. 482.

Dr. Daniels acknowledged that there is information missing from the patients' charts. Tr. 487. Dr. Daniels testified that the patient charts in this case do not include sticky notes and other notes that would have been on the inside of the manila folder that held the charts. Tr. 488. Dr. Daniels testified that a doctor learns the patient's medical history by talking to the patient about his or her past medical conditions and any current problems, to include the patient's chief complaint. Tr. 491. He stated that a doctor also acquires the patient's medical history by discussing the patient's family and social history. *Id.*

Dr. Daniels acknowledged that he did not always document the justification for the prescriptions he wrote. Tr. 523. When Dr. Daniels saw a patient at the Clinic, some of the patient's medical history was available on forms that the patient completed before the visit. Tr. 492. He explained that because he has worked in several mental health-counseling clinics, he has gained familiarity and experience in treating certain conditions. *Id.* Dr. Daniels also noted that the Clinic saw an increase in patients when it received its waiver to treat 100 patients. Tr. 489. Previously it only held a waiver for 30 patients. *Id.*

Dr. Daniels agreed with Dr. Kennedy's testimony about physical examinations. Tr. 492. Dr. Daniels testified that in situations where there is limited staff and when other patients are waiting, a doctor sometimes needs to make a ''judgment call'' about examining the patient, and not inconveniencing the waiting patients. Tr. 493. In those situations, in Dr. Daniels' view, the doctor performs ''enough of an exam'' in order to ''move forward'' with the patient, allowing the doctor time to see other patients. Tr. 493. Dr. Daniels also testified that a doctor can perform an examination by observing the patient,

not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Controlled Substances Act.'' La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1); *see also* 21 CFR 1306.04(a) (same). Therefore, the fact that Dr. Kennedy had concluded that this prescription was issued outside the usual course of professional treatment and beneath the standard of care, Tr. 602–03, demonstrates that there was a violation of law for the purpose of consideration under Factor Four of the public interest factors. *See infra* Analysis.V (Patient TC); *infra* n.27; *see also Ester Mark, M.D.,* 16,760, 16,778 (citing *Wesley Pope, M.D.,* 82 FR 14,944, 14,967 n.38 (2017) (explaining ''there is no material difference between'' the dual criteria of Section 1306.04(a).'') Prescribing a controlled substance outside the course of professional practice is enough to violate DEA's prescription requirement. *Id.*

[1] ''When an administrative tribunal elects to disregard the uncontradicted opinion of an expert, it runs the risk of improperly declaring itself as an interpreter of medical knowledge.'' *Zvi H. Perper, M.D.,* 77 FR 64131, 64140 (2012) (citing *Ross* v. *Gardner,* 365 F.2d 554 (6th Cir. 1966)).

[2] Government Exhibit 30, however, gives some support to Dr. Daniels' position that he was checking the PMP, *[at least with respect to two of the patients].

and noting the patient's demeanor, activity, mood, and physical appearance. Tr. 493–94. Sometimes, Dr. Daniels decided to do a more thorough physical examination. Tr. 512.

Dr. Daniels testified that in general he would ask each patient: About his or her medication; whether the medication was working; who initially prescribed it; and how long the patient had been taking it. Tr. 517. Similarly, Dr. Daniels testified that the purpose of checking a patient's PMP report was to see which medications, if any, the patient has received before, when the patient received those medications, and the doctors who prescribed them. Tr. 495. Although there is no requirement to print out a copy of a patient's PMP report, Dr. Daniels testified that it would be ideal to obtain a printout. Tr. 496.

Dr. Daniels testified that when searching for a patient on the PMP, he was mostly concerned with looking at the past 30 days. Tr. 496–97. It is normal to delegate the duty to check the PMP to someone other than the doctor. Tr. 497. Normally, a staff member of the Clinic would run a PMP report and provide the results to Dr. Daniels. Tr. 514, 522. The Clinic did not document the results of the PMP report. Tr. 522.

With respect to urine drug screens, Dr. Daniels testified that in most cases he addressed abnormalities with the patient but did not document that fact in the patient's chart. Tr. 498, 502. He acknowledged it would be best practice to document efforts to address an abnormal urine drug screen. Tr. 501. He also acknowledged that ''a couple of patients'' tested negative for their prescribed medications. Tr. 502. It is unclear, however, whether he was referring to the patients in this case. Testing negative for a prescribed controlled substance raises the concern of diversion. *Id.* When this occurred, he would refer it to the clinical social worker. Tr. 503. These actions, in his opinion, should have been better documented. *Id.*

Dr. Daniels testified that the current standard is not to discharge a noncompliant patient. Tr. 499–500. It was unclear from his testimony when this standard began. For example, Dr. Daniels made an analogy to a diabetic patient whose sugars are elevated after not complying with his or her prescribed diet. *Id.* Dr. Daniels said that a doctor would not discharge this patient simply because the patient failed to comply with his or her diet. Tr. 500. According to Dr. Daniels, the same is true for doctors treating patients for chemical dependency. *Id.* He explained that it is better for a patient in the long-term to be kept on medication than to discharge the patient. *Id.* Discharging a patient could lead to a relapse or to the patient taking dangerous street drugs. *Id.* In Dr. Daniels' opinion, none of the patients in this case should have been discharged because of a urine drug screen. Tr. 501–02.

Some of the patients who presented with opioid addiction also had other issues, such as anxiety and depression, and Dr. Daniels had to formulate a treatment plan for those issues as well. Tr. 506. Most of the patients also needed counseling. Tr. 501, 504, 506. If Dr. Daniels was not going to be at the Clinic, he would sometimes write a prescription for the patient and have the staff check the patient's vitals and take a urine drug screen. Tr. 508–10. If the patient was taking Suboxone, Dr. Daniels would discuss the Suboxone treatment regimen plan with the patient. Tr. 516. He would also ask the patient if he or she signed the treatment contract, and whether the patient understood it. Tr. 516. He would only address specific provisions of the treatment contract if he believed there might be a particular issue with the patient's ability to comply with the contract. Tr. 516.

When asked about the physical examination he conducted of patient AK, at AK's first visit on January 18, 2017, Dr. Daniels said he checked-off neat and clean on the record, and noted AK had a depressed affect. Tr. 512; GE–6, at 25. Patient AK also took a urine drug screen at this first visit. Tr. 514; GE–6, at 29. AK's initial urine drug screen was positive for methamphetamine, but not when he returned to the next visit. Tr. 515; GE–6, at 29. It was also positive for marijuana. *Id.* Dr. Daniels testified that he was not concerned when a patient tested positive for THC because ''it's so ubiquitous in this population that I see,'' and he did not believe it would be unsafe for AK to take marijuana. Tr. 515. Dr. Daniels' treatment plan for AK at the first visit was to conduct monthly and random urine drug screens, provide AK counseling, prescribe Subutex 8 mg TID and Klonopin 2 mg, and have AK return to the Clinic in one month. Tr. 515, 518.

Dr. Daniels could not remember what was found on AK's PMP report, if anything, because AK's PMP results are not documented. Tr. 514. Dr. Daniels testified that he was able to conclude that AK had an opioid addiction based on AK's medical history, the physical examination that Dr. Daniels described, and AK's urine drug screen. Tr. 515. AK also had an anxiety disorder and pain. Tr. 517–18. Dr. Daniels did not see pain recorded in AK's chart. Tr. 517. Dr. Daniels did not see AK's counseling records in his chart. Tr. 515–16. Dr. Daniels testified that the Food and Drug Administration has advised that patients should not be denied Subutex simply because the patient is also taking a benzodiazepine. Tr. 518. In Dr. Daniels' opinion, he believed it was justified to prescribe Subutex and Klonopin to AK because AK had pain and had taken opioids and Klonopin before. Tr. 518. Dr. Daniels acknowledged, however, that AK's chart does not document that AK had taken opioids before *[for a pain condition]. *Id.* Dr. Daniels believed prescribing a higher dose of Subutex to AK was warranted because in addition to opioid addiction AK also had pain, and Subutex can be used to relieve pain. Tr. 517–18. In Dr. Daniels' opinion, the prescriptions in Stipulation 17 were written to treat AK's substance abuse disorder, anxiety, and chronic pain. Tr. 520.

On June 22, 2016, patient CA presented with an opioid addiction, and history of abdominal pain, hand fracture, arthritis, anxiety, ADHD, and TMJ. Tr. 521. CA had received Subutex from another doctor for opioid addiction, as well as Adderall for ADHD and Klonopin for anxiety. Tr. 521–22. When asked about the physical examination he conducted of CA, Dr. Daniels testified that he looked at CA's person, place, and orientation; noted that CA's affect was ''blunted and flat''; and observed that he was ''depressed and anxious.'' Tr. 521. Dr. Daniels testified that CA's history, his answers, and his demeanor were consistent with ADHD. Tr. 523. Based on CA's history and Dr. Daniels' examination of CA, he was able to diagnose CA with an opioid addiction, anxiety disorder, and ADHD. Tr. 522. Dr. Daniels testified that CA had received treatment from another provider before CA had seen him. Tr. 528.

Dr. Daniels' treatment plan for CA included monthly urine drug screens, counseling, Subutex at his current dosage, Klonopin 1 mg TID, and Adderall 30 mg. Tr. 523. In Dr. Daniels' opinion, the prescriptions in Stipulation 22 were written to treat CA's diagnosed conditions of opioid addiction, anxiety, chronic abdominal pain, ADHD, and TMJ. Tr. 524; GE–10, at 53.

Patient MN's chief complaint was an addiction to Subutex. Tr. 526. After talking with her, he learned that she had been addicted to other medications as well. *Id.* MN had already been prescribed Subutex for opioid dependence by other doctors before seeing Dr. Daniels. Tr. 528–29. MN also had anxiety. Tr. 529. Dr. Daniels' chart for MN included a note that Suboxone

gave her migraines. Tr. 527; GE–14, at 29. Dr. Daniels described it as ''a very limited note,'' but explained that ''sometimes with interruptions in the clinic, you get limited information to put in the chart.'' Tr. 527.

When asked whether he physically encountered MN, Dr. Daniels said that he did not ''see a document of physical encounter.'' Tr. 527. Dr. Daniels testified, however, that he did see MN, and he did conduct a physical examination. Tr. 527–28. MN's chart includes some medical history collected by the Clinic's staff and the counselor. Tr. 528. When asked whether he was able to diagnose MN, he stated that he diagnosed her with an opioid addiction based on her history. Tr. 528–29. Dr. Daniels' treatment plan for MN included Subutex 8 mg TID and Klonopin. Tr. 529. In Dr. Daniels' opinion, the prescriptions in Stipulation 24 were written to treat MN's opioid dependency and anxiety. Tr. 529–30.

Patient JD presented with a history of back pain and opioid abuse. Tr. 531. JD had been prescribed Lortab for his back pain by another physician, but he later began taking Percocet and methadone, which he bought on the street. *Id.* A previous physician had also prescribed Subutex to JD for an opioid addiction, and his urine drug screen was ''consistent with having [taken] Subutex.'' Tr. 532.

Dr. Daniels' treatment plan for JD included Subutex 8 mg TID, monthly drug screens, and counseling. *Id.* He additionally testified that JD remained in the Clinic past this initial visit and that the Subutex prescription was meant to address JD's back pain as well as his addiction. Tr. 533.

Patient SB's chief complaint was panic attacks and a history of recreational drug abuse. Tr. 534. SB had been treated by another physician with Suboxone, but after experiencing side effects was treated with Subutex instead. *Id.* In addition to taking vitals, height, and weight, Dr. Daniels ordered a urine drug screen for SB. *Id.* SB tested positive for methamphetamine, marijuana, and Subutex. *Id.* While he did not make a note of it in SB's file, Dr. Daniels testified that in this situation, his general recommendation would have been for more frequent counseling. Tr. 535–36. However, he prescribed SB with Subutex for addiction, and with Klonopin for panic attacks. Tr. 535.

Patient CM came to the Clinic with a history of abusing oxycodone and roxycodone. Tr. 537. CM had previously been prescribed Subutex by another physician. *Id.* Dr. Daniels took CM's vitals, recorded height and weight, and made some other notes about CM's appearance and habits. *Id.* CM did a urine drug screen, which came back positive for marijuana and Suboxone. Tr. 538. Dr. Daniels also noted that CM ''appeared to have an anxiety disorder.'' Tr. 540.

Dr. Daniels' treatment plan for CM included Subutex for ''chemical dependencies,'' and Klonopin for anxiety. *Id.* When pressed about the Klonopin prescription, Dr. Daniels testified that Klonopin is what is usually prescribed for anxiety. Tr. 542. He also recommended counseling. Tr. 540. According to Dr. Daniels, CM remained a patient with the clinic for some time and was making progress. Tr. 539–40.

In detailing his treatment of patient JW, Dr. Daniels noted that JW was a professional colleague of his who owned the Clinic before Ms. LW took it over. Tr. 543. JW is a professional counselor who has known Dr. Daniels since 2003. *Id.* Dr. Daniels testified that JW began developing chronic pain in 2013, and a local physician was treating him with methadone. Tr. 544. JW had been referred to a pain specialist in Shreveport who was unable to see him because of an insurance issue. *Id.* Dr. Daniels agreed to see JW temporarily because he was in terrible pain and ''almost unable to ambulate.'' *Id.* Though he says it was not his intent to treat JW long term, he treated him until 2017. *Id.*

Dr. Daniels determined that JW had hypertension, lumbar disc disease, chronic back pain, a history of carpal tunnel syndrome, and multiple surgeries in the past. Tr. 547. The initial plan was to follow up on medical records. *Id.*

Dr. Daniels prescribed OxyContin to JW because he had just had knee surgery, and he was complaining of severe knee pain. Tr. 548. He chose OxyContin because JW had developed a tolerance to other pain medications. Tr. 549. He claims that he wrote the prescription for every 4–6 hours by mistake and that the usual dose is every 12 hours. *Id.* He also believes that JW was taking it ''correctly,'' meaning every 12 hours. Tr. 550. Dr. Daniels also prescribed Percocet to JW so that he could ''rotate [the pain medications] around'' for ''different options on pain relief,'' because JW described being able to take certain medications on some days, but not on others. *Id.* Dr. Daniels saw JW as a patient at least once per week, but sometimes two or three times per week, in addition to encountering him professionally on a regular basis. Tr. 550–51. On cross-examination, Dr. Daniels agreed that five of the prescriptions he wrote to JW for OxyContin were written with the wrong dosing instructions. Tr. 577–79.

When Dr. Daniels first saw the undercover agent (''TC'') as a patient, TC initially told him that he was taking 4–5 pain pills per day that he had bought off of the street, presuming them to be Lortab. Tr. 552. Dr. Daniels believed that TC would benefit from counseling. *Id.* From further conversation, Dr. Daniels got the impression that TC was actually taking more pills than he was letting on and that he was not completely sure that the pills were, in fact, Lortab. Tr. 553. TC also ''indicated that he was taking Suboxone off the street'' and ''taking maybe Adderall.'' Tr. 554. This led Dr. Daniels to prescribe Suboxone. *Id.*

TC took a urine drug screen which tested negative. Tr. 556. However, based on his understanding of ''the local people that [he] had been treating for so many years'' and TC's history, Dr. Daniels felt that the dose of Suboxone he prescribed was appropriate because he believed it to be one that would prevent a relapse. Tr. 557. Dr. Daniels testified that the reason why some of his discussions with TC did not get documented in the medical record was ''because it was cumbersome.'' Tr. 506.

As to his licensing history, Dr. Daniels testified that he had never been denied a COR. Tr. 560. Regarding his state authority, Dr. Daniels entered into a consent order with the state medical board, and he testified that there had been concerns that he was not properly monitoring patients or supervising staff. *Id.* *[He stated that the state medical board ''felt like that [he], as an individual practitioner, trusted people too much, that I gave too much confidence in the people when I would ask them to do things or expect them to bring things to me.'' Tr. 561.] Citing personal stress, Dr. Daniels testified that he ''had not be[en] able to really take full advantage of the opportunity to see these patients'' leading to potential risks given the areas he was practicing in. Tr. 561. At the state medical board's recommendation, Dr. Daniels attended continuing medical education seminars on controlled substance prescribing, ethics, and boundaries. Tr. 562. After completing these recommendations, the medical board restored his license, but he was not allowed to practice in the areas of managing: Addiction; chronic pain; or obesity. Tr. 563.

Dr. Daniels re-applied for a COR once his state license was reinstated. Tr. 564. In filling out the form, he claims he did not realize that he ''would have to be more complete'' and that he ''wasn't aware that the high risk practice areas

was where they were restricting [him].'' Tr. 565. His understanding was that the state medical board had fully reinstated his controlled substance prescribing authority. *Id.* Dr. Daniels claims that he did not intend to be evasive or misleading. *Id.* He additionally testified that he has been struggling professionally without a COR because he currently works at a diabetes management clinic where Lyrica, a Schedule V controlled substance, is an important part of treatment. Tr. 568–69.

* [Dr. Daniels testified that he felt ''like he had made every attempt to make sure that these patients were getting proper evaluations, and that the medicines that [he] was prescribing were safe and effective, and that [he] admit[s] some of the records fall short. [He] failed. But [he] feel[s] that still the overall diagnoses were correct, and the treatment plans were good.'' Tr. 570.]

Despite being the witness with the most at stake in these proceedings, and thus the witness with the strongest motive to fabricate, Dr. Daniels presented generally as candid and sincere. However, there were notable inconsistencies between his descriptions of his prescribing history to various patients and objective data such as the PMP report for the relevant period. * [Additionally, I note that regarding the undercover TC, Dr. Daniels stated, ''[a]nd he did tell me about alcohol and he was drinking. And we talked about some of the things that needed to be understood about the contract that he signed that he would not drink alcohol when taking these medicines.'' Tr. 555. However, the transcript of their recorded conversation does not reflect any mention of the contract that TC signed or not drinking alcohol when taking the medicines, despite TC bringing up his alcohol use twice in the conversation. *See* GE–25, at 3; *see also* Tr. Tr. 82–84. I find this statement to weigh against Dr. Daniels' credibility and to be an attempt to minimize the egregiousness of his actions.] Thus, I generally credit Dr. Daniels' testimony, but where his testimony conflicts with that of other witnesses or record evidence, I consider it with close scrutiny.

The Facts

I. Stipulations

The Parties agree to 49 stipulations (''Stip.''), which the Parties have accepted as facts in these proceedings. Tr. 10.

Background

1. Dr. Daniels is a physician licensed to practice medicine by the Louisiana State Board of Medical Examiners in the State of Louisiana.

2. Dr. Daniels was previously registered with the DEA to handle controlled substances in Schedules II through V under DEA COR No. AD2802937 at 1514 Doctors Drive, Bossier City, Louisiana 71111.

3. Dr. Daniels surrendered DEA COR No. AD2802937 for cause on September 29, 2017.

4. Government Exhibit No. 1 is a true and correct copy of Dr. Daniels' signed surrender of his DEA COR No. AD2802937, dated September 29, 2017.

5. On September 20, 2017, the Louisiana State Board of Medical Examiners (''LSBME'') issued a notice partially suspending Dr. Daniels' medical license and prohibiting him from ''prescribing, dispensing or administering controlled substances to any patient, effective September 21, 2017.''

6. Government Exhibit No. 2 is a true and correct copy of the notice issued by the LSBME on September 20, 2017.

7. Dr. Daniels filed a new application for a DEA COR on or about March 16, 2018.

8. Government Exhibit No. 3 is a true and correct copy of Dr. Daniels' March 16, 2018 application for a DEA COR.

9. Government Exhibit No. 4 is a true and correct copy of the Certification of Registration History showing Dr. Daniels' answers to the liability questions in his March 16, 2018 application for a DEA COR.

Consent Order

10. On March 12, 2018, the LSBME issued a Consent Order for Reprimand to Dr. Daniels that, among other things, did the following:

a. The Consent Order recalled the suspension of Dr. Daniels' authority to prescribe, dispense, or administer controlled substances issued on September 20, 2017.

b. The Consent Order accepted Dr. Daniels' representations to the LSBME that he would permanently refrain from prescribing controlled substances for chronic pain or obesity and refrain from associating himself with a drug treatment clinic.

c. The Consent Order imposed continuing restrictions on Dr. Daniels' authority to prescribe, dispense, or administer controlled substances, namely that it required Dr. Daniels to meet with the LSBME or a designee in advance and to abide by any suggestions or conditions the LSBME might recommend if Dr. Daniels ever wished to resume the acts he promised to discontinue.

11. Government Exhibit No. 5 is a true and correct copy of the Consent Order for Reprimand issued by the LSBME on March 12, 2018.

12. Dr. Daniels referenced the Consent Order, a public document, in his application for the COR.

Patient AK

13. Government Exhibit No. 6 is a true and correct copy of Dr. Daniels' patient file for Patient AK.

14. Government Exhibit No. 7 is a true and correct copy of a DEA subpoena issued to the CVS Pharmacy located at 2735 Beene Boulevard, Bossier City, Louisiana, regarding Dr. Daniels' prescriptions to Patient AK.

15. Government Exhibit No. 8 is a true and correct copy of various prescriptions that Dr. Daniels issued to Patient AK and that DEA obtained from the CVS Pharmacy located at 2735 Beene Boulevard, Bossier City, Louisiana.

16. Government Exhibit No. 9 is a true and correct copy of a DEA subpoena issued to Super One Pharmacy located at 745 Shreveport Barksdale Highway, Shreveport, Louisiana, regarding Dr. Daniels' prescriptions to Patient AK, and the response that DEA received from Brookshire Grocery Company, Pharmacy Operations, 1600 WSW Loop 323, Tyler, Texas, containing copies of prescriptions Respondent issued to Patient AK

17. As listed below, Dr. Daniels issued prescriptions for controlled substances, including Subutex (buprenorphine) and Klonopin (clonazepam), to Patient AK on at least the following occasions:

Date issued	Prescription
1/16/2017	15 units of Subutex 8 mg.
1/18/2017	90 units of Subutex 8 mg; 30 units of Klonopin 2 mg.
2/23/2017	90 units of Subutex 8 mg; 30 units of Klonopin 2 mg.
3/22/2017	90 units of Subutex 8 mg; 30 units of Klonopin 2 mg.
4/18/2017	90 units of Subutex 8 mg; 30 units of Klonopin 2 mg.
5/18/2017	90 units of Subutex 8 mg; 30 units of Klonopin 2 mg.

Date issued	Prescription
7/28/2017	90 units of Subutex 8 mg; 30 units of Klonopin 2 mg.
8/25/2017	90 units of Subutex 8 mg; 30 units of Klonopin 2 mg.

Patient CA

18. Government Exhibit No. 10 is a true and correct copy of Dr. Daniels' patient file for Patient CA.

19. Government Exhibit No. 11 is a true and correct copy of a DEA subpoena issued to Benzer Pharmacy located at 2951 E. Texas Street, Bossier City, Louisiana, regarding Dr. Daniels' prescriptions to Patient CA.

20. Government Exhibit No. 12 is a true and correct copy of various prescriptions that Dr. Daniels issued to Patient CA and that DEA obtained from Benzer Pharmacy located at 2951 E. Texas Street, Bossier City, Louisiana.

21. Government Exhibit No. 13 is a true and correct copy of a response to a DEA Subpoena from Walgreen's Pharmacy located at 9209 Mansfield Road, Shreveport, Louisiana, containing a prescription that Dr. Daniels issued to Patient CA.

22. As listed below, Dr. Daniels issued prescriptions for controlled substances, including Subutex, Klonopin, and Adderall (amphetamine-dextroamphetamine mixture), to Patient CA on at least the following occasions:

Date issued	Prescription
6/9/2016	90 units of Subutex 8 mg; 30 units of Klonopin 1 mg.
6/22/2016	90 units of Klonopin 1 mg; 30 units of Adderall 30 mg.
7/6/2016	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
8/31/2016	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
9/28/2016	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
10/26/2016	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
11/16/2016	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
12/14/2016	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
1/11/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
2/8/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
3/8/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
4/5/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
5/3/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
5/31/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
6/29/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
7/26/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
8/23/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.
9/13/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg; 30 units of Adderall 30 mg.

Patient MN

23. Government Exhibit No. 14 is a true and correct copy of Dr. Daniels' patient file for Patient MN.

24. As listed below, Dr. Daniels issued prescriptions for controlled substances, including Subutex and Klonopin, to Patient MN on at least the following occasions:

Date issued	Prescription
5/3/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
5/31/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg.
6/28/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg.
7/28/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg.
8/29/2017	90 units of Subutex 8 mg; 90 units of Klonopin 2 mg.

Patient JD

25. Government Exhibit No. 15 is a true and correct copy of Dr. Daniels' patient file for Patient JD.

26. Government Exhibit No. 16 is a true and correct copy of a response to a DEA Subpoena from Brookshire's Pharmacy located at 1125 Highway 80, Haughton, Louisiana, containing prescriptions that Dr. Daniels issued to Patient JD.

27. As listed below, Dr. Daniels issued prescriptions for controlled substances, including Subutex, to Patient JD on at least the following occasions:

Date issued	Prescription
8/3/2016	90 units of Subutex 8 mg.
8/31/2016	90 units of Subutex 8 mg.
9/28/2016	90 units of Subutex 8 mg.
10/26/2016	90 units of Subutex 8 mg.
11/16/2016	90 units of Subutex 8 mg.
12/14/2016	90 units of Subutex 8 mg.
1/18/2017	90 units of Subutex 8 mg.
2/8/2017	90 units of Subutex 8 mg.
3/8/2017	90 units of Subutex 8 mg.

Date issued	Prescription
4/5/2017	90 units of Subutex 8 mg.
5/3/2017	90 units of Subutex 8 mg.
6/7/2017	90 units of Subutex 8 mg.
7/5/2017	90 units of Subutex 8 mg.
8/2/2017	90 units of Subutex 8 mg.
8/30/2017	90 units of Subutex 8 mg.

Patient SB

28. Government Exhibit No. 17 is a true and correct copy of Dr. Daniels' patient file for Patient SB.

29. As listed below, Dr. Daniels issued prescriptions for controlled substances, including Subutex and Klonopin, to Patient SB on at least the following occasions:

Date issued	Prescription
1/18/2017	60 units of Subutex 8 mg; 60 units of Klonopin 1 mg.
2/15/2017	60 units of Subutex 8 mg; 60 units of Klonopin 1 mg.
3/15/2017	60 units of Subutex 8 mg; 60 units of Klonopin 1 mg.
4/12/2017	60 units of Subutex 8 mg; 60 units of Klonopin 1 mg.
5/10/2017	60 units of Subutex 8 mg; 60 units of Klonopin 1 mg.
6/24/2017	60 units of Subutex 8 mg; 60 units of Klonopin 1 mg.
7/19/2017	60 units of Subutex 8 mg; 60 units of Klonopin 1 mg.

Patient CM

30. Government Exhibit No. 18 is a true and correct copy of Dr. Daniels' patient file for Patient CM.

31. As listed below, Dr. Daniels issued prescriptions for controlled substances, including Subutex and Klonopin, to Patient CM on at least the following occasions:

Date issued	Prescription
5/4/2016	90 units of Subutex 8 mg.
6/1/2016	90 units of Subutex 8 mg.
6/29/2016	90 units of Subutex 8 mg.
7/27/2016	90 units of Subutex 8 mg.
8/24/2016	90 units of Subutex 8 mg.
9/21/2016	90 units of Subutex 8 mg.
10/19/2016	90 units of Subutex 8 mg.
11/16/2016	90 units of Subutex 8 mg.
12/14/2016	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
1/11/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
2/22/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
3/20/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
4/19/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
5/17/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
6/14/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
7/12/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
8/9/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.
9/5/2017	90 units of Subutex 8 mg; 60 units of Klonopin 2 mg.

Patient JW

32. Government Exhibit No. 19 is a true and correct copy of Dr. Daniels' patient file for Patient JW.

33. Government Exhibit No. 20 is a true and correct copy of a DEA subpoena issued to the CVS Pharmacy located at 1118 Homer Road, Minden, Louisiana, regarding Dr. Daniels' prescriptions to Patients CA, JD, CM, and JW.

34. Government Exhibit No. 21 is a true and correct copy of various prescriptions that Dr. Daniels issued to Patients CA, JD, CM, and JW, and that DEA obtained from the CVS Pharmacy located at 1118 Homer Road, Minden, Louisiana.

35. As listed below, Dr. Daniels issued prescriptions for controlled substances, including methadone, Percocet (oxycodone-acetaminophen), OxyContin (oxycodone extended release), and Lortab (hydrocodone-acetaminophen), to Patient JW on at least the following occasions:

Date issued	Prescription
7/5/2013	90 units of methadone 10 mg.
7/22/2013	150 units of methadone 10 mg.
8/9/2013	30 units of Percocet 10/325 mg.
8/16/2013	150 units of methadone 10 mg.
8/23/2013	60 units of Percocet 10/325 mg.

Date issued	Prescription
9/6/2013	60 units of Percocet 10/325 mg.
9/13/2013	150 units of methadone 10 mg.
10/11/2013	150 units of methadone 10 mg.
10/18/2013	60 units of Percocet 10/650 mg.
11/8/2013	150 units of methadone 10 mg; 60 units of Percocet 10/325 mg.
12/6/2013	150 units of methadone 10 mg; 60 units of Percocet 10/325 mg.
12/20/2013	60 units of Percocet 10/325 mg.
1/3/2014	150 units of methadone 10 mg; 90 units of Percocet 10/325 mg.
1/17/2014	90 units of Percocet 10/325 mg.
1/31/2014	150 units of methadone 10 mg; 90 units of Percocet 10/325 mg.
2/14/2014	90 units of Percocet 10/325 mg.
2/28/2014	90 units of Percocet 10/325 mg.
3/14/2014	30 units of OxyContin 10 mg.
3/19/2014	90 units of Percocet 10/325 mg.
3/21/2014	150 units of methadone 10 mg.
3/28/2014	20 units of OxyContin 10 mg; 90 units of Percocet 10/325 mg.
4/11/2014	20 units of OxyContin 10 mg; 90 units of Percocet 10/325 mg.
4/17/2014	150 units of methadone 10 mg.
4/25/2014	20 units of OxyContin 10 mg; 120 units of Percocet 10/325 mg.
5/9/2014	20 units of OxyContin 10 mg; 120 units of Percocet 10/325 mg.
5/16/2014	20 units of OxyContin 10 mg; 120 units of Percocet 10/325 mg.
5/23/2014	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
6/6/2014	120 units of Percocet 10/325 mg.
6/20/2014	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
7/10/2014	60 units of Lortab 10/325 mg.
7/16/2014	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
8/8/2014	120 units of Percocet 10/325 mg.
8/22/2014	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
9/5/2014	120 units of Percocet 10/325 mg.
9/19/2014	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
10/17/2014	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
11/14/2014	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
12/5/2014	120 units of Percocet 10/325 mg.
12/12/2014	150 units of methadone 10 mg.
12/23/2014	120 units of Percocet 10/325 mg.
1/5/2015	120 units of Percocet 10/325 mg.
1/12/2015	150 units of methadone 10 mg.
1/23/2015	120 units of Percocet 10/325 mg.
2/6/2015	120 units of Percocet 10/325 mg.
2/20/2015	120 units of Percocet 10/325 mg.
3/6/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
3/20/2015	120 units of Percocet 10/325 mg.
4/2/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
4/17/2015	120 units of Percocet 10/325 mg.
5/1/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
5/15/2015	120 units of Percocet 10/325 mg.
6/1/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
6/15/2015	120 units of Percocet 10/325 mg.
7/1/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
7/30/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
8/14/2015	120 units of Percocet 10/325 mg.
8/31/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
9/14/2015	120 units of Percocet 10/325 mg.
9/26/2015	150 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
10/14/2015	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
11/24/2015	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
12/9/2015	120 units of Percocet 10/325 mg.
12/19/2015	120 units of Percocet 10/325 mg.
12/30/2015	180 units of methadone 10 mg.
1/12/2016	120 units of Percocet 10/325 mg.
1/27/2016	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
2/24/2016	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
3/16/2016	120 units of Percocet 10/325 mg.
3/23/2016	180 units of methadone 10 mg.
4/6/2016	120 units of Percocet 10/325 mg.
4/27/2016	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
5/18/2016	120 units of Percocet 10/325 mg.
5/25/2016	180 units of methadone 10 mg.
6/8/2016	120 units of Percocet 10/325 mg.
6/22/2016	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
7/20/2016	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
8/10/2016	120 units of Percocet 10/325 mg.
8/24/2016	180 units of methadone 10 mg.
8/31/2016	120 units of Percocet 10/325 mg.

Date issued	Prescription
9/21/2016	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
10/5/2016	120 units of Percocet 10/325 mg.
10/26/2016	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
11/9/2016	120 units of Percocet 10/325 mg.
12/14/2016	120 units of Percocet 10/325 mg.
12/21/2016	180 units of methadone 10 mg.
1/4/2017	120 units of Percocet 10/325 mg.
1/6/2017	30 units of OxyContin 10 mg.
1/18/2017	180 units of methadone 10 mg.
1/30/2017	120 units of Percocet 10/325 mg.
2/13/2017	120 units of Percocet 10/325 mg.
2/21/2017	180 units of methadone 10 mg.
3/1/2017	120 units of Percocet 10/325 mg.
3/22/2017	180 units of methadone 10 mg; 120 units of Percocet 10/325 mg.
4/5/2017	120 units of Percocet 10/325 mg.

Patient TC

36. Government Exhibit No. 23 is a true and correct copy of Dr. Daniels' patient file for Patient TC.

37. On September 13, 2017, Dr. Daniels issued a prescription to Patient TC for 60 units of Suboxone (buprenorphine/naloxone) 8/2 mg.

38. Government Exhibit No. 24 is a true and correct video recording of Dr. Daniels' interaction with Patient TC on September 13, 2017.

39. Government Exhibit No. 25 is a true and correct transcript of Dr. Daniels' interaction with Patient TC on September 13, 2017.

40. Government Exhibit No. 27 is a true and correct video recording of Patient TC's visits to Dr. Daniels' office on September 12 and 13, 2017.

Controlled Substances

41. DEA lists Subutex (buprenorphine) as a Schedule III controlled substance under 21 CFR 1308.13(e)(2)(i).

42. DEA lists Klonopin (clonazepam) as a Schedule IV controlled substance under 21 CFR 1308.14(c)(11).

43. DEA lists Adderall (amphetamine-dextroamphetamine mixture) as a Schedule II controlled substance under 21 CFR 1308.12(d)(1).

44. DEA lists methadone as a Schedule II controlled substance under 21 CFR 1308.12(c)(15).

45. DEA lists Percocet (oxycodone-acetaminophen) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(xiii).

46. DEA lists OxyContin (oxycodone extended release) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(xiii).

47. DEA lists Lortab (hydrocodone-acetaminophen) as a Schedule II controlled substance under 21 CFR 1308.12(b)(1)(vi).

48. DEA lists Suboxone (buprenorphine/naloxone) as a Schedule III controlled substance under 21 CFR 1308.13(e)(2)(i).

49. Respondent's Exhibit No. 2 is a true and correct copy of a March 9, 2018 letter from Dr. Daniels' counsel to Cecilia Mouton, M.D., the Director of Investigations for the Louisiana State Board of Medical Examiners, and which is countersigned by Cecilia Mouton, M.D., on behalf of the Louisiana State Board of Medical Examiners.

II. Findings of Fact

The Application

1. Dr. Daniels has never been denied a COR. Tr. 560.

2. Dr. Daniels entered into a consent order with the State Medical Board (''the Board''), following concerns that he was not properly monitoring patients or supervising staff. Tr. 560.

3. At the Board's recommendation, Dr. Daniels attended continuing medical education seminars on controlled substance prescribing, ethics, and boundaries. Tr. 562. After completing those seminars, the Board restored Dr. Daniels' medical license, but he was not allowed to practice in the areas of managing: Addiction; chronic pain; or obesity. Tr. 563.

4. Dr. Daniels re-applied for a COR once his license was reinstated. Tr. 564. In filling out the application, he did not realize that he ''would have to be more complete'' and that he was not ''aware that the high risk practice areas was where they were restricting [him].'' Tr. 565. His understanding was that the Board and the State Pharmacy Board had fully reinstated his controlled substance prescribing authority. *Id.*

5. The application for a COR does not inform an applicant to provide the detailed information that the DEA asserted was missing from Dr. Daniels' application. Tr. 70.

6. The information Dr. Daniels provided on his application placed the DEA on notice that it should not summarily approve Dr. Daniels' application, but rather that DEA should investigate it. Tr. 70–71.

7. Dr. Daniels did not intend to be evasive or misleading when he submitted his application for a Certificate of Registration. Tr. 565.

8. Dr. Daniels is struggling professionally without a COR because he currently works at a diabetes management clinic where Lyrica, a Schedule V controlled substance, is an important part of treatment. Tr. 568–69.

The Clinic

9. The Clinic was located in Minden, Louisiana, which is a rural area. Tr. 480.

10. LW had full control of the Clinic from April 2017 to September 2017. Tr. 479.

11. The Clinic provided services for low, to mid-level, income individuals, but it focused its service on those with low incomes. Tr. 421. The Clinic provided services to a wide array of patients including those suffering from drug addiction and those with mental health problems. Tr. 421–22. Most of the patients had some type of opioid addiction. Tr. 424. The Clinic stayed open late on Wednesdays to make it convenient for patients to seek treatment. Tr. 422–23.

12. Dr. Daniels would see patients at the Clinic one day a week, arriving around 5:00 p.m., and staying until 9:00 to 10:00 p.m. Tr. 424–25. Dr. Daniels was scheduled to see 25 patients a week, but sometimes he saw more. Tr. 425.

13. Dr. Daniels was the only physician who worked at the Clinic. Tr. 425. Most of the patients he saw had some kind of opioid addiction. Tr, 427.

14. The Clinic also employed a licensed practical nurse, a registered nurse, a licensed clinical social worker, a receptionist, and a phlebotomist. Tr. 425–26.

15. The Clinic struggled with establishing a reliable system for

ensuring the patients' charts were complete and accurate. Tr. 486–87.

16. The entire staff of the Clinic worked on medical records, but the Clinic brought in an RN to work on the records because the Clinic had seen a lot of deficiencies in the records. Tr. 427. These changes were made after LW began working full-time in the Clinic. Tr. 428. As of April 2017, the Clinic was attempting to organize and re-structure. Tr. 435.

17. Various employees at the Clinic inserted documents into the patients' charts as well as taking the patient's vital signs. Tr. 437–38. The office staff as a whole was responsible for making sure the documents got into the patient's medical record. Tr. 438.

18. The registered nurse was hired to audit the medical records, and she was also in the office with Dr. Daniels when he saw patients. Tr. 436.

19. When a patient came into the Clinic, the licensed clinical social worker would conduct a clinical/behavioral assessment to determine whether the patient met the criteria to be treated at the Clinic. Tr. 429, 443.

20. Most of the Clinic's patients had previously been seen at other clinics. Tr. 429.

21. All new patients were required to submit urine samples for drug screening. Tr. 432, 443. The results of the screening were passed on to the licensed clinical social worker. *Id.*

22. The phlebotomist did the urine drug screens and bloodwork. Tr. 441.

23. If a patient met the Clinic's requirements, the patient was scheduled to see Dr. Daniels. Tr. 432.

24. Dr. Daniels wanted to see the patients' vitals, as well as their drug screens. Tr. 438.

25. The work that the Clinic employees performed was at Dr. Daniels' request. Tr. 441. Information gathered in the assessments was provided to Dr. Daniels. Tr. 441–42.

26. Generally, PMPs were tracked for each patient and if anything was out of line Dr. Daniels was informed. Tr. 442, 446. Of the patients named in the Order to Show Cause, however, Dr. Daniels' PMP account was used to check the prescriptions filled by only two patients, CA and TC. Tr. 597–99; GE–30. The PMP was checked for both of these patients on September 13, 2017, which was the last day CA received a prescription from Dr. Daniels, and the only time he issued a prescription to TC. Tr. 598; GE–30, at 2; Stip. 22, 37.

27. The Clinic's default setting used for reviewing PMPs was one year, but Dr. Daniels was more concerned about what a patient had received within the last 30 days. Tr. 496–97.

28. Normally a staff member of the Clinic would run a PMP report and provide the results to Dr. Daniels. Tr. 448, 497, 514, 522. The results of the PMP report would not be documented. Tr. 522.

29. Ideally, a doctor gets a print-out of a patient's PMP report, but there is no requirement to print it out. Tr. 496.

30. The Clinic did not check a patient's PMP when the patient came in to pick up a prescription. Tr. 451.

Dr. Daniels' Clinic Practices

31. Dr. Daniels used Suboxone and Subutex to treat opioid addiction. Tr. 506.

32. Dr. Daniels did not put together the patient charts at the Clinic. Tr. 485–86.

33. Dr. Daniels acknowledged that there is information missing from the patients' charts. Tr. 487. Dr. Daniels testified that the patient charts in this case do not include sticky notes and other notes that would have been on the inside of the manila folder that held the charts. Tr. 488.

34. When Dr. Daniels saw a patient at the Clinic, some of the patient's medical history was available on forms that the patient completed before the visit. Tr. 492.

35. In general, Dr. Daniels would ask each patient: About his or medication; whether the medication was working; who initially prescribed it; and how long the patient had been taking it. Tr. 517.

36. Dr. Daniels testified that a doctor can perform an examination by observing the patient, and noting the patient's demeanor, activity, mood, and physical appearance. Tr. 493–94. Sometimes Dr. Daniels decided to do a more thorough physical examination. Tr. 512.

37. Dr. Daniels testified that in situations where there is limited staff and other patients are waiting, a doctor sometimes needs to make a ''judgment call'' about examining the patient, and not inconveniencing waiting patients. Tr. 493. In that situation, in Dr. Daniels' view, the doctor performs ''enough of an exam'' in order to ''move forward'' with the patient, allowing the doctor time to see other patients. Tr. 493.

38. With respect to urine drug screens, Dr. Daniels testified that he was provided the results of the screens. Tr. 510. He testified that in most cases he addressed abnormalities with the patient, but did not document that fact in the patient's chart. Tr. 498, 502, 510. He acknowledged it would be best practice to document efforts to address an abnormal urine drug screen. Tr. 501.

39. Dr. Daniels testified that the current standard is to not discharge a patient who is noncompliant with the treatment plan. Tr. 499–500.

40. In Dr. Daniels' view, it is better to keep a long-term patient on medication than to discharge the patient. Tr. 500. Discharging a patient could lead to a relapse, or to the patient taking dangerous street-drugs. *Id.*

41. If the new patient was already taking Suboxone, Dr. Daniels would discuss the Suboxone treatment regimen plan with the patient. Tr. 516. He would also ask the patient if he or she signed the treatment contract, and whether the patient understood it. *Id.* He would only address specific provisions of the treatment contract if he believed there might be a particular issue with the patient's ability to comply with the contract. *Id.*

42. Dr. Daniels reviewed the PMP to: See what medications a patient has been on; determine previous providers; and, determine when the patient received medications. Tr. 495.

43. When one of Dr. Daniels' substance-abuse patients tested positive for marijuana he did not address the issue with the patient because it was ''so ubiquitous in the population'' that Dr. Daniels treated. Tr. 515.

44. While working at the Clinic, Dr. Daniels was under quite a bit of personal stress and he ''had not be[en] able to really take full advantage of the opportunity to see these patients,'' which lead to potential risks given the areas in which he was practicing. Tr. 561.

General Facts Derived From Expert Testimony

45. Klonopin (clonazepam) is a benzodiazepine. Tr. 177.

46. To prescribe controlled substances in Louisiana for the treatment of chemical dependency, the standard of care requires the treating physician to: conduct an adequate physical examination; obtain past medical records; obtain PMP reports; conduct drug screening; and maintain medical records. Tr. 141–42, 492.

47. The standard of care requires that a patient's medical record be ''complete and accurate.'' Tr. 151.

48. A doctor need not document everything that occurred during a patient encounter, but the doctor should document the important, pertinent information that will give an objective viewer a picture of what happened during the encounter. Tr. 151–52.

49. Changes in medical treatment, and the reasons for those changes, must be documented. Tr. 150. The treatment plan is updated over time. *Id.*

50. When there is a consistent absence of pertinent information in a patient's medical records such as: PMP reports; a credible physical examination; past medical records; resolution of abnormal drug screens, the records reach a point where it is not possible to say that the treatment has been within the scope of acceptable medical practice or that the prescriptions are legitimate. Tr. 154; *see also* Tr. 384.

51. Because the application of medicine needs to be individualized, a sufficiently adequate physical examination would not necessarily be the same for every patient. Tr. 144–45, 492.

52. In conducting a physical examination for a patient who has chemical dependency the doctor should: Look for track marks; note how the patient's pupils look and whether the patient's mucous membranes are dry; look for goosebumps; look for signs of withdrawal such as whether the patient is sweaty and/or shaky, and/or whether the patient is obtunded. Tr. 143, 289, 492. Much of this information can be obtained through a discussion with the patient. Tr. 290, 492. If the chemical dependency originated following treatment of an injury to a part of the body, the physical examination should also include an examination of that body part. Tr. 388–89, 492.

53. As part of a physical examination for a patient who has a chemical dependency, a doctor should ask the patient questions such as: What are you using?; How long have you been using?; Why did you start using?; Are you around people who are using?; and, How do the drugs affect your life? Tr. 144, 492.

54. It is possible to treat a patient even without obtaining prior medical records; however, contained within the patient's medical records should be a documented good-faith effort to obtain the prior records, and an explanation of why treatment has begun without those prior records. Tr. 292.

55. Obtaining past medical records is important because such records contain an abundance of information that a treating doctor needs to know. Tr. 145. Obtaining past medical records is mandatory. Tr. 146. Even if the patient presents with medical documentation, the physician is not relieved of the obligation to attempt to obtain past medical records. Tr. 291.

56. A physician also needs to take a medical history and/or look for past medical records upon the patient's initial visit. Tr. 146. It is also important to update the patient's medical history. Tr. 147.

57. The failure to take a medical history, and/or to obtain past medical records, makes it difficult to argue that the doctor knows what he or she is doing at any particular instance of the patient's care. Tr. 147.

58. In Louisiana, the treatment plan must talk about what is being done for a patient, and why. Tr. 148, 503. The treatment plan allows another physician to pick up the patient's record and understand the treatment. Tr. 148–49. The treatment plan assists with continuity of care. Tr. 149.

59. For a patient with a chemical dependency, the treatment plan is dependent on what has been done in the past, and where the medical treatment is intended to take the patient. Tr. 149. *[For opioid addiction, Dr. Kennedy testified that in a treatment plan, he ''would expect there to be goals as far as where it is that we're heading with this. In other words, is this somebody that we expect that we're going to wean and discharge from this medication eventually? What are the likelihood of doing dosage adjustments if it works or if it doesn't work? What are we going to do if the patient has problems with some social issue . . . . All of the other kind of things that would go into any treatment record, where you're hoping that the patient is going to have an improved life.'' Tr. 301]

60. Informed consent is not obtained by having a signature on a form. Tr. 306. Informed consent is obtained by a conversation between the physician and the patient in which the doctor explains the dangers, the side effects of treatment, and that the treatment might not work. *Id.*

61. A prescription itself is not sufficient documentation of medical treatment. Tr. 234.

62. In Louisiana, a doctor who is treating a patient for addiction or chemical dependency is required to document the results of an abnormal urine drug screen, and the actions the physician took in response to it. Tr. 173, 225–26. If the test is abnormal, the results must be documented, as well as documenting the type of action that was taken in response to the abnormal test. Tr. 310–11, 318, 336, 378. Ignoring an abnormal urine drug screen, or saying nothing about it, is outside the course of acceptable medical practice in Louisiana. Tr. 378. *[Regarding the standard of care for chemical dependency, Dr. Kennedy stated, ''If we're talking about treating patients with chemical dependency, with the way that the regulations, the way the systems are designed, there's a reason we have to check PDMP reports and there's a reason that we have to get drug screens and there's a reason that we have to get past medical records and all of these other things, and it's not because we're counting on the patients being compliant, it's because of the likelihood of patients being noncompliant.'' Tr. 299.]

63. For a doctor to treat a diagnosis there must be supporting information. Tr. 323. A diagnosis alone is not sufficient to support a prescription for controlled substances. Tr. 371.

64. A clinical licensed social worker cannot make a diagnosis. Tr. 408. Thus, the diagnosis made by the social worker contained in Government Exhibit 14, pages 31–39, is not a valid diagnosis. *See also* Tr. 380 (no evidence that Dr. Daniels reviewed the diagnosis).

65. Prior to 2018, doctors in Louisiana were not required to check a patient's PMP before writing a prescription for a controlled substance, but it was considered the standard of care. Tr. 393.

66. The use of multiple pre-signed medical forms and/or identical copied handwritten treatment notes do not support a finding of legitimate medical care and are not credible in medical records. Tr. 190, 196; *cf.* GE–6 at 12, GE–14, at 14, and GE–18, at 26; and GE–6, at 26, and GE–10, at 57.

67. Signed forms do not provide sufficient advice concerning the dangers of combining alcohol with buprenorphine when the patient had a history of abusing drugs, and an abnormal urine drug screen. Tr. 400. A discussion needs to occur because the patient is starting a program of regular scheduled medications. Tr. 401. If, later, it is determined that the patient is still abusing drugs, it is clear the original discussion was not enough, and the doctor needs to revisit the issue with the patient. *Id.*

68. Signed forms are not sufficient to constitute a treatment plan. Tr. 374.

69. A Patient Treatment Contract does not establish a physician/patient relationship. Tr. 304.

70. None of the patients' medical records in the Administrative Record contained sufficient documentation to support a prescription for Klonopin. Tr. 399–400.

The Patients

Patient AK

71. On January 16, 2017, AK signed a Patient Treatment Contract with Dr. Daniels. Tr. 161, 303–04; GE–6, at 30. In paragraph one of that contract, AK agreed to keep, and be on time, for all of his scheduled appointments, and in paragraph two he agreed to the payment policy of Dr. Daniels' office. *Id.* In paragraph 13 of the contract, AK agreed

to abstain from alcohol, opioids, marijuana, cocaine, and other addictive substances. *Id.* This contract was signed by Dr. Daniels on January 18, 2017. Tr. 162; GE–6, at 30.

72. Paragraph 10 of the Patient Treatment Contract that AK signed on January 16, 2017, reads as follows: ''I understand that mixing buprenorphine with other medications especially benzodiazepines (for example, Valium, Klonopin, or Xanax), can be dangerous. I also recognize that several deaths have occurred among persons mixing buprenorphine and benzodiazepines (especially if taken outside the care of a physician, using a route of administration other than sublingual or in higher than recommended therapeutic doses).'' GE–6, at 30.

73. On January 16, 2017, AK signed a Patient Agreement to Participate in Suboxone Treatment. Tr. 161, 308; GE–6, at 31. At the end of each paragraph is a space for the patient's initials, but there are no initials there. Tr. 308; GE–6, at 31.

74. On January 16, 2017, AK signed a Patient Information and Consent to Treatment with Buprenorphine and Suboxone. GE–6, at 41. The fourth paragraph of that information sheet advises that combining buprenorphine with alcohol or other sedating medications is dangerous, and that combining buprenorphine with benzodiazepines has resulted in deaths. *Id.*

75. The prescription that Dr. Daniels wrote for AK on January 16, 2017, for 15 tablets of 8 mg Subutex predates any written documentation of Dr. Daniels actually seeing AK. Tr. 160–61; GE–9, at 10; Stip. 17. Because this prescription was written prior to Dr. Daniels initially seeing AK, this prescription was issued outside of the course of medical practice in the state of Louisiana, and it was not issued for a legitimate medical purpose. Tr. 162–63, 401–02.

76. The initial Physician Intake Note for AK, dated January 18, 2017, indicates that AK had a history of multiple fractures, secondary to a fight and a motor vehicle accident. Tr. 162, 511; GE–6, at 25. The Note also indicates that AK had an opioid addiction issue, and that he previously took prescriptions for 8 mg Subutex, three times a day, and for 2 mg Klonopin, once a day. Tr. 165, 302, 511; GE–6, at 25; *see also* GE–6, at 43. The treatment history indicated that AK had previously been treated by another provider. Tr. 165, 511; GE–6, at 25. It does not appear that Dr. Daniels obtained treatment records from that provider. Tr. 165–66; GE–6. The Authorization to Release Healthcare Information in AK's file was not completed. Tr. 167; GE–6, at 47.

77. Dr. Daniels testified that he was able to conclude that AK had an opioid addiction based on AK's medical history, the physical examination that Dr. Daniels described, and AK's urine drug screen. Tr. 515.

78. Dr. Daniels testified that, even though the documentation is limited, AK also had an anxiety disorder and pain, and that the pain was related to AK's fractures. Tr. 517–18. Dr. Daniels did not see pain recorded in AK's chart.[3] Tr. 517.

79. Dr. Daniels testified that the Food and Drug Administration has advised that patients should not be denied Subutex simply because the patient is also taking a benzodiazepine. Tr. 518. In Dr. Daniels' opinion, he believed it was justified to prescribe Subutex and Klonopin to AK because he had pain and had taken opioids and Klonopin before. Tr. 518. Dr. Daniels acknowledged, however, that AK's chart does not document that AK had taken opioids before *[for a pain condition]. *Id.*

80. Dr. Daniels believed prescribing a higher dose of Subutex to AK was warranted because in addition to opioid addiction, AK also had pain and Subutex can be used to relieve pain. Tr. 517–19.

81. The initial Physician Intake Note for AK, dated January 18, 2017, contains a treatment plan that reads, ''Monthly and random drug screens. Counseling with LW Medical Multi Care Clinic 801 Shreveport Rd. Minden, La. One group monthly 6:00–7:30 p.m. Meet with LPC 20 minutes prior to doctor visit.''[4] Tr. 169, 302–03; GE–6, at 25. The treatment plan also includes the medications prescribed, but it does not include a rationale as to why the medications were prescribed. *Id.* Dr. Daniels testified that AK's treatment plan developed on January 18, 2017, was to conduct monthly and random urine drug screens, provide AK counseling, prescribe Subutex 8 mg TID and Klonopin 2 mg, and have AK return to the Clinic in one month. Tr. 515, 518; GE–6, at 25.

82. Contained in AK's medical file is a Physician Assessment form dated January 18, 2017. Tr. 164; GE–6, at 45–46. Although this assessment is contained in AK's patient file, his name is not on the form, and the form is not signed by a doctor. *Id.* The form also does not document that Dr. Daniels performed a physical examination of AK. *Id.*

83. The only portion of a physical examination documented in AK's medical record for his first visit on January 18, 2017, was that AK appeared neat and clean, and that he had a depressed affect. Tr. 512; GE–6, at 25.

84. Dr. Daniels did not know whether the Klonopin AK reported he had been taking had been prescribed to him, or if he was taking it ''off the street.'' Tr. 511–12.

85. AK's PMP was not checked at the Clinic. Tr. 168, 597–99; GE–30.

86. On January 18, 2017, AK's urine drug screen was positive for benzodiazepines, methamphetamine, THC, and Subutex. Tr. 169–70, 514; GE–6, at 29. In his ''MD Notes'' for that day, Dr. Daniels wrote that AK's drug screen was positive for Subutex and negative for opioids.[5] *Id.* at 26. This was an abnormal drug screen because it was positive for methamphetamine and THC (''marijuana''). Tr. 170–72. In that AK had indicated that he had not used crystal methamphetamine, the results of the urine drug screen should make a physician very suspicious that AK was lying. Tr. 171–72; GE–6, at 39. There is no indication in AK's medical record that Dr. Daniels took any action in response to AK's abnormal drug screen. Tr. 174.

87. On February 23, 2017, and March 22, 2017, AK's urine drug screens were positive for benzodiazepines, THC and Subutex. GE–6, at 27–28. In his treatment notes for those days, Dr. Daniels wrote that AK's drug screen was positive for Subutex and negative for opioids. *Id.* at 26.

88. On a Pharmacy Prior Authorization Form, dated April 3, 2017, Dr. Daniels notes that AK had reported adverse reactions to Suboxone. GE–6, at 24.

89. On June 20, 2017, AK's urine drug screen was positive for benzodiazepines and Subutex. Tr. 309; GE–6, at 6.

90. On September 25, 2017, Dr. Daniels discharged patient AK for failing to keep agreed appointments every 28 days, and/or for not paying in full for his office visits in a timely manner. GE–6, at 6.

91. A review of Dr. Daniels' medical records of AK reveals no documentation that Dr. Daniels ever conducted a physical examination of AK, and those records provide no justification for Dr.

[3] Assuming that AK was in pain, a physical examination should have included an examination of AK's body parts that had been fractured. Tr. 388–89, 492. No such examination, however, is documented in AK's medical record. GE–6.

[4] This treatment plan will be referred to as the ''boilerplate treatment plan'' throughout the remainder of this Recommended Decision.

[5] This note makes little sense, however, because Subutex is an opioid. Tr. 177.

Daniels' prescription of Klonopin to AK. Tr. 396–97; GE–6, at 1–49.

92. The prescriptions that Dr. Daniels wrote for AK on January 18, 2017, for Klonopin and Subutex were not issued for a legitimate medical purpose because: action taken on the abnormal urine drug screen, if any, was not documented; the PMP was not checked; there were no past medical records; and there was no documentation of a significant physical examination. Tr. 177; GE–30.

93. A Physician Intake Note dated June 20, 2017, is contained in AK's patient file. Tr. 180; GE–6, at 12. This is the only other intake note contained in AK's patient file. Tr. 182; GE–6, at 12. Prior to this date, Dr. Daniels issued prescriptions to AK on six occasions, and after this date on two more occasions. Tr. 181; Stip. 17.

94. The Physician Intake Note of June 20, 2017, does not document: A physical examination; AK's response to prior treatment; a rationale for the prescriptions; or the response to abnormal drug screens. Tr. 182–84; GE–6, at 11, 12, 27–28.

95. Although the Physician Intake Note of June 20, 2017, is signed, it is not dated, and the signature is identical to that contained on an intake note of patient MN, dated June 28, 2017, and an intake note of patient CM, dated August 9, 2017, and the signatures on both of those intake forms are not dated. Tr. 186–89; GE–6 at 12; GE–14, at 14; GE–18, at 26.

96. Dr. Daniels also used identical copied handwritten ''boilerplate'' notes concerning patients' monthly counseling appointments. Tr. 193–95; *cf.* GE–6, at 26, and GE–10, at 57. Such notes are not credible in medical records. Tr. 196.

97. The prescriptions that Dr. Daniels issued to AK between January 16, 2017 and August 25, 2017, identified in Stipulation 17, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose because Dr. Daniels did not: conduct a sufficient medical history of AK; conduct a physical examination of AK; formulate a treatment plan with a rationale that supported the prescriptions; document resolution of abnormal urine drug screens; obtain prior medical records or conduct a review of AK's PMP; or maintain accurate medical records. Tr. 191–92.

Patient CA

98. On June 9, 2016, CA signed a Patient Treatment Contract with Dr. Daniels. GE–10, at 56. In paragraph 13 of the contract, CA agreed to abstain from alcohol, opioids, marijuana, cocaine, and other addictive substances. *Id.*

99. Paragraph 10 of the Patient Treatment Contract that CA signed on June 9, 2016, reads as follows: ''I understand that mixing buprenorphine with other medications especially benzodiazepines (for example, Valium, Klonopin, or Xanax), can be dangerous. I also recognize that several deaths have occurred among persons mixing buprenorphine and benzodiazepines (especially if taken outside the care of a physician, using a route of administration other than sublingual or in higher than recommended therapeutic doses).'' GE–10, at 55.

100. On June 9, 2016, CA signed a Patient Information and Consent to Treatment with Buprenorphine and Suboxone. GE–10, at 76. The fourth paragraph of that information sheet advises that combining buprenorphine with alcohol or other sedating medications is dangerous, and that combining buprenorphine with benzodiazepines has resulted in deaths. *Id.*

101. On June 9, 2016, CA's urine drug screen tested positive for only buprenorphine. GE–10, at 93–95. This was abnormal based on the medications that CA reported he was taking. Tr. 217–18.

102. The prescriptions that Dr. Daniels wrote for CA on June 9, 2016, for Klonopin and Subutex predate any written documentation of Dr. Daniels actually seeing CA. Tr. 204; Stip. 22. Because these prescriptions were written prior to Dr. Daniels initially seeing CA, these prescriptions were issued outside of the course of medical practice in the State of Louisiana, and they were not issued for legitimate medical purposes. Tr. 204, 401–02.

103. On June 22, 2016, an assessment was completed for CA. Tr. 196; GE–10, at 51–53. The assessment indicates that CA had an opioid (oxycodone) addiction, and that another doctor had given CA a prescription for Subutex. Tr. 197, 521; GE–10, at 51. The assessment indicates that CA became addicted to oxycodone while being treated for abdominal pain, a hand fracture, and arthritis. Tr. 196, 521; GE–10, at 51. The assessment also indicates that CA had a history of ADHD for which he was taking Adderall, and he was taking Klonopin for anxiety. Tr. 196, 521–22, 524; GE–10, at 51. CA also had a history of TMJ. Tr. 521; GE–10, at 51. The assessment does not document a physical examination that would support prescriptions for controlled substances. Tr. 196–97; GE–10, at 53. The assessment also does not document a rationale for the controlled substances that Dr. Daniels prescribed. Tr. 198–99; GE–10, at 51–53. Because CA's chart does not support a diagnosis of ADHD, there is nothing in CA's chart that justified a prescription for Adderall. Tr. 322, 377.

104. The comments' section of the June 22, 2016 assessment is a handwritten partial treatment plan.[6] Tr. 406–07; GE–10, at 51–53. What is missing is a notation of follow-up, anticipated reaction to things that may go wrong or if the patient needs more medication. Tr. 407; *see also* Tr. 503. In addition, Louisiana law details specific information that must be contained in a treatment plan. *See* La. Admin. Code tit. 46, Pt. XLV, § 6921(A)(3).

105. Although the June 22, 2016 assessment indicated that another doctor had treated CA, there are no prior medical records in CA's medical file, nor was there a request for those records in the file. Tr. 197–98.

106. Dr. Daniels viewed CA's history, his answers, and his demeanor as being consistent with ADHD. Tr. 523. Based on CA's history and Dr. Daniels' examination of CA, he diagnosed CA with an opioid addiction, anxiety disorder, and ADHD. Tr. 522.

When asked about the physical examination he conducted of CA, Dr. Daniels testified that he looked at CA's person, place, and orientation; noted that CA's affect was ''blunted and flat''; and observed that he was ''depressed and anxious.'' Tr. 521. This information was obtained from CA's mental status examination, however, not from a physical examination. Tr. 582; GE–10, at 52.

107. Dr. Daniels' treatment plan for CA included monthly urine drug screens, counseling, Subutex at his current dosage, Klonopin 1 mg TID, and Adderall 30 mg. Tr. 523; GE–10, at 53. Dr. Daniels acknowledged, however, that the justification for these prescriptions is not contained in CA's medical records. *Id.* He further testified these prescriptions were written to treat CA's medical condition he had diagnosed: Opioid addiction, anxiety, chronic abdominal pain, TMJ, and ADHD. Tr. 524; GE–6, at 53.

108. CA's medical file contains a Physician Intake Note dated July 26, 2017. Tr. 199; GE–10, at 34. The intake note contains the boilerplate treatment plan. GE–10, at 34. The intake note does not document: A physical examination; CA's responses to past treatment; or a

[6] This partial treatment plan is the same plan that is preprinted on Physician Intake Forms–the boilerplate treatment plan. *See, e.g.,* GE–6, at 25; GE–10, at 23.

rationale for the prescriptions that Dr. Daniels issued to CA. Tr. 199; GE–10, at 34. In addition, the length of time between this documented encounter with CA and the previous documented encounter (more than a year), during which CA continued to get the same three prescriptions every month, is not consistent with the standard of care. Tr. 205–06; Stip. 22.

109. CA's medical file contains a Physician Intake Note dated September 13, 2017. Tr. 200; GE–10, at 23. The intake note contains the boilerplate treatment plan. GE–10, at 23. The intake note does not document: A physical examination,*E or a rationale for the prescriptions that Dr. Daniels issued to CA. Tr. 201; GE–10, at 23. It does have a comment that CA reported zero problems with current meds. *Id.* That comment, however, does not provide sufficient follow-up or history of his prior treatment with Dr. Daniels. Tr. 201–202.

110. On June 9, 2016, CA's urine drug screen was positive for only buprenorphine. Tr. 217; GE–10, at 93–94. This was an abnormal urine drug screen because it was inconsistent with the medications he told the doctor he had been previously prescribed. Tr. 217–18.

111. On September 29, 2016, CA's urine drug screen was positive for only Subutex. Tr. 212; GE–10, at 87. This was an abnormal urine drug screen because it was inconsistent with the medications he was prescribed, whereas earlier tests were positive for those same medications. Tr. 212–13.

112. On October 18, 2016, November 16, 2016, December 7, 2016, and January 4, 2017, CA's urine drug screens were positive for benzodiazepines, Subutex, and methamphetamine. Tr. 208–212; GE–10, at 72–74, 97. *[Although CA was taking amphetamines, Dr. Kennedy testified that this would not make the urine drug test positive for methamphetamines. Tr. 209. Additionally, he testified that ''this is an inconsistent result and we have to send it out to disprove that notion.'' Tr. 210.]

113. A treatment note of January 11, 2017, indicates that CA was receiving a prescription of Adderall for ADHD, and a prescription of Klonopin for anxiety. GE–10, at 64. Someone other than Dr. Daniels signed this note. *Id.*

114. On May 2, 2017, CA's urine drug screen was positive for Subutex, but negative for Adderall and Klonopin. Tr. 216; GE–10, at 18. CA had received prescriptions for all of these medications on April 5, 2017. GE–10, at 6. The results of this urine drug screen were abnormal. Tr. 216. On May 3, 2017, an unsigned, handwritten treatment note for CA indicates that his drug screen was positive, but does not indicate what it was positive for. GE–10, at 57. The treatment note also incorrectly indicates that the drug screen was negative for opioids. *Id.*

115. On July 26, 2017, CA's urine drug screen was positive for buprenorphine, but negative for amphetamines and benzodiazepines. Tr. 216–17; GE–10, at 28, 30. CA had received prescriptions for all types of these medications on June 29, 2017. GE–10, at 3. The results of this urine drug screen were abnormal. Tr. 216–17.

116. On August 23, 2017, CA's urine drug screen was positive for buprenorphine, but it was negative for amphetamines and benzodiazepines. Tr. 214; GE–10, at 11–12. CA had received prescriptions for all types of these medications on July 26, 2017. GE–10, at 2. The results of this test were not normal. Tr. 214–15.

117. A review of Dr. Daniels' medical records of CA reveals no documentation that Dr. Daniels ever conducted a physical examination of CA, and those records provide no explanation of why Dr. Daniels prescribed Klonopin to him, other than CA's claim that he had a history of ADHD and anxiety, which was unsupported by any records. GE–10, at 1–97, 51; Tr. 322. *[The record does contain vital signs for CA, which Dr. Kennedy described as ''part'' of the physical examination. Tr. 316; GE–10, at 51.]

118. There are no discussions of any abnormal urine drug screens in CA's medial file. Tr. 214–15, 220. The failure to respond or document that response to abnormal urine drug screens makes it very difficult to conclude that the physician is engaged in ''legitimate medical management in a patient who's receiving scheduled medications for any reason.'' Tr. 219.

119. Between June 2016 and September 2017, Dr. Daniels was issuing CA prescriptions for Subutex, Klonopin, and Adderall, an opioid, a benzodiazepine, and an amphetamine. Tr. 203; Stip. 22.

120. In Dr. Kennedy's opinion, all the prescriptions Dr. Daniels wrote for CA, identified in Stipulation 22, were issued outside the course of medical practice and were not issued for a legitimate medical purpose. Tr. 206–07, 220.

Patient MN

121. On May 2, 2017, MN presented to the Clinic needing help with withdrawal symptoms due to a history of opioid dependence. GE–14, at 19. She stated that she was addicted to Subutex, which she claimed to have been taking for two years. *Id.* MN also reported that she had taken Klonopin in the past for depression and anxiety and was requesting a refill. *Id.*

122. On May 2, 2017, MN signed a Patient Treatment Contract with Dr. Daniels. Tr. 327–28; GE–14, at 43. In paragraph 13 of the contract, MN agreed to abstain from alcohol, opioids, marijuana, cocaine, and other addictive substances. GE–14, at 43. Although MN signed this contract, it was not signed by Dr. Daniels or anyone else. *Id.*

123. Paragraph 10 of the Patient Treatment Contract that MN signed on May 2, 2017, reads as follows: ''I understand that mixing buprenorphine with other medications especially benzodiazepines (for example, Valium, Klonopin, or Xanax), can be dangerous. I also recognize that several deaths have occurred among persons mixing buprenorphine and benzodiazepines (especially if taken outside the care of a physician, using a route of administration other than sublingual or in higher than recommended therapeutic doses).'' GE–14, at 43.

124. MN's medical file contains an assessment completed by a licensed clinical social worker on May 2, 2017. GE–14, at 19–28, 31–39.

125. On May 3, 2017, MN's urine drug screen was positive for ecstasy, THC, and Subutex. Tr. 222, 327; GE–14, at 41. The presence of ecstasy and marijuana indicates that MN was abusing drugs. Tr. 222.

126. On May 3, 2017, Dr. Daniels entered a ''very limited note'' [7] in MN's medical record that Suboxone gave MN headaches. Tr. 527, 583–84; GE–14, at 29. The note does not include a subjective complaint, any objective findings, any assessment of MN's conditions, or a medical treatment plan. GE–14, at 29. That same day, Dr. Daniels wrote prescriptions to MN for 8 mg Subutex TID, and 2 mg Klonopin BID. Stip. 24; GE–14, at 5. Then on May 31, 2017, Dr. Daniels again wrote a prescription to MN for 8 mg Subutex TID, but he modified the prescription for 2 mg Klonopin to TID. GE–14, at 4; Stip. 24. Because these prescriptions were written prior to Dr. Daniels documenting sufficient information into MN's medical record, these prescriptions were issued outside of the usual course of professional practice in

*E Although vital signs were taken for CA, Dr. Kennedy testified that they are not adequate to support the provision of controlled substances. Tr. 376–77; GE–10, at 51.

[7] Dr. Daniels explained that it was a limited note because ''sometimes with interruptions in the clinic, you get limited information to put in the chart.'' Tr. 527.

the State of Louisiana, and not for a legitimate medical purpose. Tr. 163, 401–02.

127. MN's medical file contains a Physician Intake Note dated June 28, 2017. Tr. 221; GE–14, at 14. The intake note contains the boilerplate treatment plan. GE–14, at 14. The intake note does not document: A physical examination; MN's responses to past treatment; or a rationale for the prescriptions that Dr. Daniels issued to MN. GE–14, at 14. The MD note of May 3, 2017, and this intake note are the only notes in MN's file that document an encounter between Dr. Daniels and MN. Tr. 221; GE–14.

128. When asked whether he had a physical encounter with MN, Dr. Daniels testified that he did not ''see a document of physical encounter.'' Tr. 527. Although there is no documentation of a physical encounter, he testified that he did see her and he did conduct a physical examination.[8] Tr. 527–28. Dr. Daniels also testified, however, that he diagnosed MN as having an opioid addiction based on her history. Tr. 528–29.

129. There is nothing in Dr. Daniels' medical record concerning MN that documents that Dr. Daniels diagnosed MN's medical condition. Tr. 582.

130. A treatment plan for MN would have included a discussion of how Dr. Daniels was going to wean MN off of Subutex, the substance she claimed she was addicted to. Tr. 408–09. As of May 3, 2017, Dr. Daniels' treatment plan for MN only included Subutex 8 mg TID and Klonopin. Tr. 529; GE–14, at 29.

131. On June 28, 2017, MN's urine drug screen was positive for only Subutex. Tr. 223; GE–14, at 10. This drug screen was abnormal because it should have been positive for a benzodiazepine, having received a prescription for Klonopin on May 31, 2017. Tr. 223–24; Stip. 24.

132. On July 28, 2017, MN's urine drug screen was positive for ecstasy, Subutex, and methamphetamines, and negative for benzodiazepines. Tr. 224; GE–14, at 8. This is a ''wildly abnormal'' drug screen. Tr. 224–25. *[Dr. Kennedy testified that ''to have a drug screen like this, and to make absolutely no comment in the medical record, did not make any comment with addressing the patient about it, or what you plan to do about this, is in my view, inexcusable.'' Tr. 226. Further, he stated that ''to continue providing this patient with scheduled medications without comment, in my view, is not medically legitimate.'' *Id.*]

133. On August 29, 201[7]*, MN received prescriptions for Subutex and Klonopin, written by Dr. Daniels, but there is no documentation in MN's medical file of an encounter with Dr. Daniels that day. Tr. 228; GE–14, at 1; Stip. 24. *[Dr. Kennedy testified that ''every single prescription for a scheduled medication, in my opinion, must be accounted for.'' Tr. 233. He clarified that when writing new prescription, there must be something documenting that prescription in the medical record. *Id.*]

134. There are no discussions of any abnormal urine drug screen in MN's medical file. Tr. 226–27; GE–14. The failure to respond or document a response to abnormal urine drug screens makes it very difficult to conclude that the physician is engaged in ''legitimate medical management in a patient who's receiving scheduled medications for any reason.'' Tr. 219.

135. A review of Dr. Daniels' medical records of MN reveals no documentation that Dr. Daniels ever conducted a physical examination of MN, and those records provide no explanation of why Dr. Daniels prescribed Klonopin to her, other than that she had been prescribed it in the past, and she had requested a refill. GE–14, at 1–47, 19.

136. In Dr. Kennedy's opinion, all the prescriptions identified in Stipulation 24, issued to MN, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. Tr. 231. Dr. Kennedy's opinion was based upon: The absence of drug screening documentation; the absence of medical records; no documentation that MN's PMP was reviewed; no evidence of a credible physical examination; and the absence of any documented discussions with MN that would establish a valid doctor-patient relationship. Tr. 231–32.

Patient JD

137. On August 3, 2016, JD signed a Patient Treatment Contract with Dr. Daniels. GE–15, at 30. In paragraph 13 of the contract, JD agreed to abstain from alcohol, opioids, marijuana, cocaine, and other addictive substances. *Id.*

138. Paragraph 10 of the Patient Treatment Contract that JD signed on August 3, 2016, reads as follows: ''I understand that mixing buprenorphine with other medications especially benzodiazepines (for example, Valium, Klonopin, or Xanax), can be dangerous. I also recognize that several deaths have occurred among persons mixing buprenorphine and benzodiazepines (especially if taken outside the care of a physician, using a route of administration other than sublingual or in higher than recommended therapeutic doses).'' GE–15, at 30.

139. On August 3, 2016, JD signed a Patient Information and Consent to Treatment with Buprenorphine and Suboxone. GE–15, at 32. The fourth paragraph of that information sheet advises that combining buprenorphine with alcohol or other sedating medications is dangerous, and that combining buprenorphine with benzodiazepines has resulted in deaths. *Id.*

140. On August 3, 2016, JD signed a Patient Agreement to Participate in Suboxone Treatment. Tr. 332; GE–15, at 29. At the end of each paragraph is a space for the patient's initials, but there are no initials there. *Id.* Dr. Daniels did not sign the Agreement; a counselor signed it instead. GE–15, at 29.

141. On August 3, 2016, JD presented to Dr. Daniels with a history of back pain, and indicated that he had a prior prescription for Lortab. Tr. 235, 531; GE–15, at 22. JD also reported that he had taken Percocet and methadone off the streets, and that he had used Subutex for two years. *Id.* Dr. Daniels signed and dated this handwritten assessment on August 10, 2016. Tr. 235; GE–15, at 22–23. This is the only documented encounter between JD and Dr. Daniels. Tr. 235; GE–15.

142. A review of Dr. Daniels' medical records of JD reveals no documentation: That he obtained JD's prior medical records; that Dr. Daniels ever conducted a physical examination of JD; [*F] or that he developed an appropriate treatment plan for JD. Tr. 235–36; GE–15, at 1–35.

143. Dr. Daniels' assessment of JD does not document a treatment plan (other than the boilerplate treatment plan) and it does not provide a rationale for the controlled substances prescribed to JD. Tr. 236, 330, 532; GE–15, at 22–23.

144. On August 3, 2016, JD's urine drug screen was positive for only Subutex. Tr. 532; GE–15, at 26. A counselor signed this urine drug screen. Tr. 330; GE–15, at 26. A physician should have signed the urine drug screen. Tr. 331, 380–81.

145. Over the 13 months that Dr. Daniels treated JD, there is only one encounter note. Tr. 235, 237; GE–15. Dr. Kennedy testified that one encounter followed by a year's worth of the maximum dosage of buprenorphine, is clearly outside the course of acceptable

[8] Earlier, however, Dr. Daniels testified that, ''After looking at the notes, I just remember the encounter. I don't remember from just my memory though.'' Tr. 525.

[*F] The JD file does include vital signs, which Dr. Kennedy testified is part of the physical examination, but not adequate by itself to meet the standard of care and usual course of professional practice. Tr. 329; GE–15, at 22.

medical practice anywhere in the United States. Tr. 238–39.

146. In Dr. Kennedy's opinion, all the prescriptions Dr. Daniels issued to JD, identified in Stipulation 27, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. Tr. 238. Dr. Kennedy's opinion was based upon the absence of follow-up care after the initial encounter. *Id.*

Patient SB

147. On January 17, 2017, SB signed a Patient Treatment Contract with Dr. Daniels. Tr. 340; GE–17, at 17. In paragraph 13 of the contract, SB agreed to abstain from alcohol, opioids, marijuana, cocaine, and other addictive substances. GE–17, at 17.

148. Paragraph 10 of the Patient Treatment Contract that SB signed on January 17, 2017, reads as follows: ''I understand that mixing buprenorphine with other medications especially benzodiazepines (for example, Valium, Klonopin, or Xanax), can be dangerous. I also recognize that several deaths have occurred among persons mixing buprenorphine and benzodiazepines (especially if taken outside the care of a physician, using a route of administration other than sublingual or in higher than recommended therapeutic doses).'' GE–17, at 17.

149. On January 17, 2017, SB signed a Patient Agreement to Participate in Suboxone Treatment. Tr. 337–38; GE–17, at 18. At the end of each paragraph is a space for the patient's initials, but only half of the spaces were initialed. *Id.* A counselor signed this Agreement, rather than Dr. Daniels. GE–17, at 18.

150. On January 17, 2017,[*G] SB signed a Patient Information and Consent to Treatment with Buprenorphine and Suboxone. GE–17, at 31. The fourth paragraph of that information sheet advises that combining buprenorphine with alcohol or other sedating medications is dangerous, and that combining buprenorphine with benzodiazepines has resulted in deaths. *Id.*

151. On a January 18, 2017 Physician Intake Note, Dr. Daniels noted that SB had a history of recreational drug abuse, heroin abuse, and severe panic attacks. Tr. 239, 333, 533–34; GE–17, at 15. The Note states that SB had previously been treated with Suboxone, but developed hives as a side effect. Tr. 534; GE–17, at 15. This Note is the only documentation of Dr. Daniels' assessment of SB, other than an undated, unsigned ''Physician Assessment'' in SB's medical file that does not bear the name of a patient. Tr. 239–40; GE–17, at 27–28. Neither the Note nor the Assessment documents a physical examination of SB. Tr. 240, 333; GE–17, at 15, 27–28. In addition, neither the Note nor the Assessment documents a rationale for the medications Dr. Daniels prescribed to SB. Tr. 243; GE–17, at 15, 27–28.

152. Although the Intake Note indicates that SB was treated with Suboxone in Dallas, the medical records request form was not completed and there are no prior medical records in SB's medical file. Tr. 241; GE–17, at 29.

153. On January 18, 2017, SB's urine drug screen tested positive for methamphetamine, THC and Subutex. Tr. 336, 534; GE–17, at 16. Dr. Daniels did not document any discussions with SB about this abnormal urine drug screen. Tr. 243. In light of this abnormal drug screen, Dr. Daniels should have provided a rationale for his decision to treat SB. Tr. 337. On July 14, 2017, SB's urine drug screen tested positive for Klonopin, Subutex, fluoxetine, norfluoxetine, and cTHC. GE–17, at 8, 10–11. The lab report indicates that a source for fluoxetine includes Prozac. *Id.* at 8. On her patient intake form, SB indicated that she had previously taken Prozac. *Id.* at 24–25.

154. While Dr. Daniels did not make a note of it in the file, he testified that the general recommendation for a drug screening that was positive for marijuana and methamphetamine would have been more frequent counseling.[9] Tr. 534–35.

155. A review of Dr. Daniels' medical records of SB reveals no documentation that Dr. Daniels ever conducted a physical examination of SB, and those records provide no explanation of why Dr. Daniels prescribed Klonopin to her, other than that she had a history of severe panic attacks. GE–17, at 1–32, 15.

156. In Dr. Kennedy's opinion, all the prescriptions issued to SB, identified in Stipulation 29, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. Tr. 244. Dr. Kennedy's opinion was based upon SB being a young woman of reproductive age, who had a history of heroin abuse, issues with alcohol, an abnormal drug screen, and an absence of documentation to explain treatment. *Id.* *[Dr. Kennedy testified that, ''there was, in essence, in [his] view, no medical care here, simply the provision of scheduled prescriptions.'' *Id.*]

Patient CM

157. On May 2, 2016, CM's urine drug screen tested positive for buprenorphine and cTHC. GE–18, at 34, 36.

158. On May 3, 2016, CM signed a Patient Treatment Contract with Dr. Daniels. GE–18, at 45. In paragraph 13 of the contract, CM agreed to abstain from alcohol, opioids, marijuana, cocaine, and other addictive substances. *Id.*

159. Paragraph 10 of the Patient Treatment Contract that CM signed on May 3, 2016, reads as follows: ''I understand that mixing buprenorphine with other medications especially benzodiazepines (for example, Valium, Klonopin, or Xanax), can be dangerous. I also recognize that several deaths have occurred among persons mixing buprenorphine and benzodiazepines (especially if taken outside the care of a physician, using a route of administration other than sublingual or in higher than recommended therapeutic doses).'' GE–18, at 45.

160. On May 3, 2016, CM signed a Patient Information and Consent to Treatment with Buprenorphine and Suboxone. GE–18, at 41. The fourth paragraph of that information sheet advises that combining buprenorphine with alcohol or other sedating medications is dangerous, and that combining buprenorphine with benzodiazepines has resulted in deaths. *Id.* A counselor signed this Agreement, rather than Dr. Daniels. *Id.*

161. On May 3, 2016, CM signed a Patient Agreement to Participate in Suboxone Treatment. GE–18, at 42. At the end of each paragraph is a space for the patient's initials, but there are no initials there. *Id.* A counselor signed this Agreement, rather than Dr. Daniels. *Id.*

162. A May 4, 2016 nursing assessment indicates that CM had been abusing oxycodone and Roxicodone, and he had been taking Subutex 8 mg for three years. Tr. 341, 537; GE–18, at 49. The individual who completed this

[*G] It appears that the patient mistakenly marked this with the year 2016 and so I have edited the RD to reflect 2017. In GE–17, at 17, the patient's signature year of ''16'' is crossed out and hand-edited to state ''17'' and the physician's signature lists 2017. *See* GE–17, at 17 and 18. The record demonstrates that SB first came to the clinic in January 2017. It is logical, based on these other records, that the patient was simply confused about the new year in signing this form.

[9] The medical records in this case, however, do not document an instance where Dr. Daniels increased the frequency of counseling based upon an abnormal urine drug screen. Further, although SB had an abnormal urine drug screen on January 18, 2017, GE–17, at 13, *see supra* FF 154, SB's treatment plan with respect to counseling is identical to those of other patients who had not initially tested positive for marijuana or methamphetamines. GE–10, at 34; GE–17, at 15; GE–23, at 8. In fact, Dr. Daniels' medical records concerning SB do not document that she ever returned to the Clinic for follow-up treatment or counseling, though she did receive monthly prescriptions of Subutex and Klonopin for another six months after her initial appointment. GE–17; Stip. 29.

nursing assessment did not sign or date it.[10] Tr. 251; GE–18, at 50. This nursing assessment is not sufficient to support issuing prescriptions for controlled substances to CM. Tr. 250–51. The nursing assessment indicates that a different provider had previously treated CM. Tr. 253, 537–38; GE–18, at 49. The assessment does not contain any diagnoses or a treatment plan. GE–18, at 50.

163. The prescriptions that Dr. Daniels wrote for CM on May 4, 2016, through May 17, 2017, for Subutex and Klonopin predate any written documentation of Dr. Daniels actually seeing CM. GE–18; Stip. 31. These prescriptions were issued outside the usual course of medical practice in the state of Louisiana. Tr. 401–02.

164. On December 14, 2016, Dr. Daniels began prescribing Klonopin to CM. Tr. 254; Stip. 31. Nothing in Dr. Daniels' medical records concerning CM supports prescribing Klonopin to him. Tr. 254, 542; GE–18. In fact, there are no treatment notes concerning CM dated December 14, 2016. GE–18.

165. CM's medical file contains a Physician Intake Note, dated June 14, 2017. Tr. 251, 343; GE–18, at 26. Although the intake note is signed by Dr. Daniels, the signature appears to be photocopied, and it is not dated. Tr. 251. The note contains the boilerplate treatment plan. GE–18, at 26. The note does not document: A physical examination; CM's responses to past treatment; or a rationale for the prescriptions that Dr. Daniels issued to CM. Tr. 252–54; GE–18, at 26.

166. CM's medical file contains a Physician Intake Note, dated August 9, 2017. Tr. 251–52; GE–18, at 20. This note reports that the patient was doing well on medications. GE–18, at 20. Although Dr. Daniels signed the note, the signature appears to be a photocopy, and it is not dated. Tr. 252, 340. The note contains the boilerplate treatment plan. GE–18, at 20. The intake note does not document: A physical examination; CM's responses to past treatment; or a rationale for the prescriptions that Dr. Daniels issued to CM. Tr. 252–54; GE–18, at 20.

167. There is no completed medical records' release form contained in CM's medical file. Tr. 253–54; GE–18. There are no prior medical records contained in CM's medical file. Tr. 253–54; GE–18.

168. On May 17, 2017, July 12, 2017, and September 5, 2017, CM's urine drug screens tested positive for THC (tetrahydrocannabinol) and Subutex. Tr. 538–39; GE–18, at 19, 23, 32. Although counseling would have been Dr. Daniels' normal response, he did not indicate that it was done, nor is it documented. Tr. 539; GE–18.

169. On September 9, 2017, CM's urine drug screen tested positive for benzodiazepines, THC, and Subutex. GE–18, at 21.

170. Dr. Daniels testified that CM was prescribed 8 mg Subutex TID, for his substance abuse issues, and he was eventually prescribed Klonopin for his anxiety. Tr. 540.

171. In Dr. Kennedy's opinion, all the prescriptions Dr. Daniels issued to CM, identified in Stipulation 31, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. Tr. 255. Dr. Kennedy's opinion was based upon: The lack of PMP reports in CM's file; the lack of prior medical records, the failure to document responses to abnormal urine drug screen, as well as ''other modalities'' he previously testified about. Tr. 255–56.

Undercover Patient TC

172. A DEA Task Force Officer (''TFO'') conducted two undercover visits with Dr. Daniels. Tr. 76–77, 80. The TFO presented himself to Dr. Daniels as patient TC. *Id.*

173. TC first visited Dr. Daniels' practice on September 12, 2017. Tr. 77. TC made an audio and video recording of the visit. *Id.*; GE–24, 27.

174. When TC went to the Clinic on September 12, 2017, a nurse instructed him to provide a urine sample. Tr. 77. After TC provided a urine sample, the nurse checked his vitals, and TC's blood pressure was found to be about 190/120. Tr. 78. That was the only physical examination conducted of TC. *Id.*

175. TC's urine drug screen was negative. Tr. 89; GE–23, at 9. TC reported he had not used any controlled substances in the prior two-three weeks. Tr. 89–90; GE–23, at 9; GE–25, at 1–2.

176. After TC's vitals were taken, he met with a counselor for 10 to 15 minutes. Tr. 78–79. The counselor asked him questions about his family and alcohol/substance use. *Id.* TC did not record this portion of the visit to the Clinic. *Id.* Following the interview with the counselor, the counselor indicated there was no problem. Tr. 79–80.

177. TC told the counselor that he had an addiction to Lortab and he wanted to get off it right away. Tr. 87; GE–23, at 2. TC also informed the counselor that about four years ago he began buying Lortabs off the street. Tr. 87–88; GE–23, at 2.

178. On September 12, 2017, TC signed a Patient Treatment Contract with Dr. Daniels. Tr. 90–91; GE–23, at 16. In paragraph 13 of the contract, TC agreed to abstain from alcohol, opioids, marijuana, cocaine, and other addictive substances. Tr. 91, 104; GE–23, at 16. No one at the Clinic discussed the content of the contract with TC, he was just told to sign it. Tr. 102–03.

179. Paragraph 10 of the Patient Treatment Contract that TC signed on September 12, 2017, reads as follows: ''I understand that mixing buprenorphine with other medications especially benzodiazepines (for example, Valium, Klonopin, or Xanax), can be dangerous. I also recognize that several deaths have occurred among persons mixing buprenorphine and benzodiazepines (especially if taken outside the care of a physician, using a route of administration other than sublingual or in higher than recommended therapeutic doses).'' Tr. 90; GE–23, at 16.

180. On September 12, 2017, TC signed a Patient Information and Consent to Treatment with Buprenorphine and Suboxone. Tr. 91–92; GE–23, at 17. The fourth paragraph of that information sheet advises that combining buprenorphine with alcohol or other sedating medications is dangerous, and that combining buprenorphine with benzodiazepines has resulted in deaths. *Id.* No one from the Clinic signed this form. *Id.* No one at the Clinic discussed the content of the form with TC, they just told him to sign it. Tr. 102–03.

181. On September 12, 2017, TC signed a Patient Agreement to Participate in Suboxone Treatment. Tr. 348–49; GE–23, at 19. At the end of each paragraph is a space for the patient's initials, and TC initialed each space. GE–23, at 19. Although the form was witnessed, Dr. Daniels did not sign as the witness. *Id.*

182. On September 12, 2017, Dr. Daniels' Clinic completed a Behavioral Health Assessment of TC. GE–23, at 2. The assessment was conducted by Akee Jackson. *Id.* at 6. TC's chief complaint was that he was addicted to Lortab and he wanted to get off it right away. *Id.* at 2. TC reported that he had last used Lortab two weeks prior to the assessment. *Id.*

183. On September 12, 2017, TC's urine drug screen tested negative for all drugs. Tr. 257, 556; GE–23, at 9. Based on when TC reported that he had last used an opioid, he would have been an opioid naïve patient on September 12, 2017. Tr. 258.

184. TC returned to the Clinic on September 13, 2017. Tr. 80–81. When

[10] Dr. Daniels testified, however, that this was the encounter note for the initial visit. Tr. 537. There is no Physician Intake Note concerning CM in the medical file contemporaneous with Dr. Daniels' initiation of care for CM.

TC entered Dr. Daniels' office, he asked to step out for a second. Tr. 81. He momentarily stepped out of Dr. Daniels' office to turn on his recording devices. *Id.*

185. On his second visit to the Clinic, no one took TC's vitals or conducted a physical examination of him before he saw Dr. Daniels. Tr. 81.

186. On September 13, 2017, the Clinic checked the PMP concerning TC. Tr. 598; GE–30, at 2. The medical records that Dr. Daniels maintained on TC did not contain a PMP report concerning TC. Tr. 261; GE–23. Dr. Daniels did not mention the PMP report when he met with TC on that date. GE–25.

187. On September 13, 2017, Dr. Daniels completed a Physician Intake Note concerning TC. Tr. 256; GE–23, at 8. Dr. Daniels noted that TC had a history of recreational drug abuse, and that he had positive signs of withdrawal, to include: Migraine headaches, elevated blood pressure, and sweating. GE–23, at 8; *see also* GE–25, at 4. The Intake Note does not reflect a diagnosis for TC, or document that Dr. Daniels conducted a physical examination of TC. Tr. 256–57; GE–23, at 8. In addition, a review of the video recording of this visit by TC with Dr. Daniels shows that TC met with Dr. Daniels for 8 minutes, 36 seconds, and that no physical examination [*H] was conducted, TC and Dr. Daniels just talked. Tr. 84; GE–27.

188. During the September 13, 2017 office visit, TC informed Dr. Daniels that he had provided a drug screen and that he drinks alcohol. Tr. 82. TC also informed Dr. Daniels that he had taken Suboxone or Subutex before and that he had taken it ''from people.'' Tr. 82–83; GE–25, at 2. Dr. Daniels responded by saying ''okay.'' *Id.* TC told Dr. Daniels that he had been taking 8 mg Suboxone off the street, and that he had not had any adverse reaction. Tr. 83; GE–25, at 2.

189. During the September 13, 2017 office visit, TC informed Dr. Daniels that he had been taking Lortabs, but he had not taken any for several weeks. Tr. 82, 552; GE–23, at 8; GE–25, at 1. TC also informed Dr. Daniels that he had taken Adderall before. Tr. 84; GE–25, at 3.

190. During the September 13, 2017 office visit, Dr. Daniels informed TC several times that he did not think TC's condition was very severe and that he would like to get TC some counseling. Tr. 93–94, 552; GE 25, at 3–4. TC then gave Dr. Daniels indications that his condition was more serious than he had previously been telling Dr. Daniels. Tr. 94–95, 554.

191. During the September 13, 2017 office visit, Dr. Daniels did not counsel TC about the dangers of using alcohol while taking Suboxone. GE–25. Combining alcohol with Suboxone could be dangerous. Tr. 263–64; GE–23, at 17.

192. During the September 13, 2017 office visit, Dr. Daniels did not counsel TC about the dangers of obtaining drugs off the street, or the dangers of mixing controlled substances. Tr. 83–84.

193. On September 13, 2017, Dr. Daniels issued TC a prescription for 60 tablets of 8/2 mg Suboxone, to be taken twice a day. Tr. 261–62; GE–23, at 1; Stip. 37. *[''8 milligrams twice daily, that would be, as you said, 16 milligrams a day.'' Tr. 262]

194. Dr. Daniels did not document a rationale for the prescription for the Suboxone he issued to TC. Tr. 260. Dr. Daniels did, however, ask TC appropriate questions when he met with him on September 13, 2017. Tr. 261, 349; GE–25.

195. Dr. Daniels testified, however, that based on his understanding of ''the local people that [he] had been treating for so many years,'' and TC's history, Dr. Daniels felt that the dose of Suboxone he prescribed to TC was appropriate because he believed it to be one that would prevent a relapse. Tr. 556–57.

196. Because TC was opioid naïve, if he took the Suboxone as it had been prescribed to him by Dr. Daniels, TC could have become quite sick. Tr. 262–63, 399.

197. None of the records that Dr. Daniels maintained concerning TC document a physical examination of TC. Tr. 257; GE–23. Concerning TC, Dr. Daniels should have documented a physical examination that included: Checking heart and lungs, checking for tremors in the eyes, and checking peripheral pulses for tachycardia. Tr. 389–90.

198. The medical records that Dr. Daniels maintained on TC did not contain any medical records from TC's prior doctors, but TC also told Dr. Daniels that he did not have a primary care doctor, and that he had never been treated for substance abuse. Tr. 261; GE–23; GE–25, at 3–4.

199. In Dr. Kennedy's opinion, the prescription Dr. Daniels issued to TC, identified in Stipulation 37, was issued outside the course of acceptable medical practice and was not issued for a legitimate medical purpose. Tr. 261, 266. Dr. Kennedy's opinion was based upon: The lack of PMP reports in CM's file; the lack of prior medical records; the failure to perform a physical examination; giving a high dose of Suboxone to an asymptomatic patient who has a history of recreational substance abuse; *[the lack of actual counseling regarding the dangers of mixing alcohol and Suboxone] and the deficiency of Dr. Daniels' medical records concerning TC. Tr. 261, 264–66, 386–87, 602.

200. Upon learning that TC's PMP report was checked, and after listening to Dr. Daniels' testimony, Dr. Kennedy stated that he still believes that the prescription of 16 mg of Suboxone to an opioid naïve patient was outside the standard of care, however, as to the question of ''whether or not it was issued for a legitimate medical purpose, that I would have to go over everything again to make a final decision on.'' Tr. 602.

Patient JW [11]

201. JW owned the Clinic before LW took it over. Tr. 543. JW is a professional counselor who Dr. Daniels had known and worked with since 2003. *Id.*

202. In 2013, JW developed chronic pain and a local physician treated him with methadone. Tr. 544. JW was referred to a pain specialist in Shreveport who was unable to see him because of an insurance issue. *Id.* Dr. Daniels agreed to see JW on a temporary basis because JW was in terrible pain and was ''almost unable to ambulate.'' *Id.* Although Dr. Daniels did not intend to treat JW long term, he treated JW until 2017. *Id.*

203. On July 5, 2013, JW presented to Dr. Daniels with complaints of back, arm, hand, knee, and leg pain. GE–19, at 11, 21.

204. On July 5, 2013, Dr. Daniels conducted a physical examination of JW. GE–19, at 9–10, 21. JW rated his pain as 8/10, and reported that he had surgeries performed on his back, shoulder, and a hernia. *Id.* at 21. JW reported that he was taking 10 mg methadone five times a day for chronic pain and carpal tunnel syndrome. *Id.* Following the physical examination, Dr. Daniels reached the following clinical impressions concerning JW's conditions: Hypertension; lumbar disc

[*H] Dr. Kennedy testified that although he thought that the interview of TC was appropriate, the physical examination needed to be done, and that would have included generally ''a heart and lung exam, and the doctor look in his eyes and notice if there is any kind of tremoring going on and maybe check peripheral pulses and see if he's tachycardic, and if not a complete and in-depth physical exam, at least a checking over of the patient before you embark on this program of long-term scheduled medications.'' Tr. 389–90.

[11] With respect to patient JW, the Government's only concern is with the OxyContin prescriptions that Dr. Daniels issued to JW. Tr. 547–48. Therefore, the facts concerning JW will focus on just those prescriptions.

disease; chronic back pain; history of carpal tunnel syndrome; and a history of multiple surgeries. Tr. 547; GE–19, at 9–10, 21; *see also* Patient Questionnaire, *Id.* at 26–32.

205. On July 5, 2013, Dr. Daniels placed a note in JW's medical file indicating that JW was the former patient of another doctor, but JW was well-known to Dr. Daniels. Tr. 545–46; GE–19, at 83. The note indicated that JW needed follow up for medical problems including knee and leg pain, back pain, and carpal tunnel syndrome, with the pain rating of 8/10. *Id.* Dr. Daniels noted that JW's activities of daily living were poor. *Id.*

206. A progress note for JW, dated January 31, 2014, indicates that JW presented with complaints of constant right knee pain, which he rated as 8/10. GE–19, at 103. Upon examination, Dr. Daniels noted that JW's pulse was 80, and his blood pressure was 130/82. *Id.* Dr. Daniels noted that JW's right knee was swollen, that there was increased pain with motion, and that JW was walking with a noticeable limp. *Id.* Dr. Daniels refilled prescriptions for JW for 90 tablets of 10/325 mg Percocet, and 150 tablets of 10 mg methadone. *Id.*

207. On February 20, 2014, JW had a total knee replacement of his right knee. GE–19, at 101.

208. On March 14, 2014, JW complained of very intense knee pain, which he numerically rated a 9 out of 10. GE–19, at 99. Upon examination, Dr. Daniels noted no swelling but a reduced range of motion, status-post knee surgery. *Id.* On that date, Dr. Daniels issued JW a prescription for 30 tablets of OxyContin, to be taken twice a day. *Id.*

209. Progress notes from March 28, 2014, for JW reveal complaints of occasional severe knee pain for which he needs 10 mg OxyContin, but his routine chronic pain was relieved by 10/325 mg Percocet. Tr. 548–49; GE–19, at 100. Upon physical examination, JW's pulse was 84, and his blood pressure was 146/90. *Id.* JW's knee surgery was healing well, but there was increased limited range of motion. *Id.* There was tenderness over the medial collateral ligament, and the strength was 4/5. *Id.* Dr. Daniels gave JW prescriptions for 90 tablets of 10 mg OxyContin, and 90 tablets of 10/325 mg Percocet. *Id.; see also* Stip. 35.

210. Dr. Daniels prescribed OxyContin to JW because he had just had knee surgery and was complaining of severe knee pain. Tr. 548. He chose OxyContin because JW had developed a tolerance to other pain medications. Tr. 549. Dr. Daniels claims that he wrote the dosing instructions for the prescription, to be taken every 4–6 hours, by mistake, and that he knows that the usual dose is every 12 hours. *Id.* Dr. Daniels also believed that JW was taking the OxyContin ''correctly,'' meaning every 12 hours.[12] Tr. 550, 577–79.

211. While JW was taking the OxyContin, Dr. Daniels encountered JW, either professionally or as a patient, almost daily. Tr. 550–51.

212. OxyContin is a long-acting continuous release medication indicated for patients who need around-the-clock pain management. Tr. 268. It is not appropriate to prescribe OxyContin to be taken ''as needed.'' Tr. 272. It is not appropriate to prescribe OxyContin for breakthrough pain. Tr. 272–73, 372. OxyContin has a ''Black Box Warning'' that it is not intended to be taken ''as needed,'' and that it could be dangerous to take it that way. Tr. 273. Any physician prescribing OxyContin should know that it is not to be prescribed to be taken ''as needed.'' Tr. 274.

213. The prescription that Dr. Daniels issued to JW on March 14, 2014, for OxyContin, was issued with instructions to take them as the medications are intended to be used, one tablet every 12 hours. Tr. 275–76; GE–19, at 99; Stip. 35.

214. The prescriptions that Dr. Daniels issued to JW on March 28, 2014, April 11, 2014, April 25, 2014, May 9, 2014, May 16, 2014, and January 6, 2017, for OxyContin were issued with instructions that the OxyContin was to be taken every four to six hours for severe breakthrough pain. Tr. 277–82; GE–19, at 94–97, 174; GE–21, at 75. A prescription for OxyContin should never be written like this. Tr. 278. It would be dangerous to issue a patient a prescription like this. *Id.* These prescriptions were not issued within the usual course of professional practice and were not issued for a legitimate medical purpose. Tr. 278–83, 372–73.

[12] The timing of JW obtaining new prescriptions for OxyContin lends support to this belief. On March 28, 2014, April 11, 2014, April 25, 2014, May 9, 2014, and May 16, 2014, JW received prescriptions for 20 tablets of OxyContin. Stip. 35. If JW had been taking the tablets four to six times a day, he would have run out of the medication before he returned to Dr. Daniels for a new prescription. The intervals between these appointments are 13 days, 14 days, 14 days, and 7 days. Furthermore, the dosing instructions of the March 14, 2014 prescription of 30 tablets, were to take one tablet twice a day. GE–19, at 99. Thus, that prescription was a fifteen-day supply. JW returned 14 days later to obtain a new prescription. Stip. 35. There are, however, no treatment notes concerning the stand-alone prescription for 30 tablets of OxyContin on January 6, 2017. On January 17, 2016, Dr. Daniels noted that JW ''takes meds appropriate.'' GE–19, at 60.

Analysis

To deny an application for a COR, the Government must prove, by a preponderance of the evidence, that the requirements for registration are not satisfied. *Steadman* v. *SEC,* 450 U.S. 91, 100–02 (1981); 21 CFR 1301.44(d). Under 21 U.S.C. 823(f), the DEA may deny a COR application if the ''issuance of such registration . . . would be inconsistent with the public interest.'' The DEA considers the following five factors to determine whether granting a registration is in the public interest:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to 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.

21 U.S.C. 823(f).

The DEA considers these public interest factors separately. *Ajay S. Ahuja, M.D.,* 84 Fed Reg. 5479, 5488 (2019); *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *DEA,* 412 F.3d 165, 173–74 (DC Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.,* 58 FR 37,507, 37,508 (1993). Thus, there is no need to enter findings on each of the factors. *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Furthermore, there is no requirement to consider a factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76–77 (4th Cir. 1988). When deciding whether registration is in the public interest, the DEA must consider the totality of the circumstances. *See generally Joseph Gaudio, M.D.,* 74 FR 10,083, 10,094–95 (2009) (basing sanction on all evidence of record).

The Government bears the initial burden of proof, and must justify denial by a preponderance of the evidence. *Steadman,* 450 U.S. at 100–03. If the Government presents a *prima facie* case for denying a COR application, the burden of proof shifts to the applicant to show that such action would be inappropriate. *Med. Shoppe—Jonesborough,* 73 FR 364, 387 (2008); *see, e.g., Steven M. Abbadessa, D.O.,* 74 FR 10,077, 10,078, 10,081 (2009). An applicant may prevail by successfully attacking the veracity of the OSC's allegations or the Government's evidence. *Superior Pharmacy I &*

Superior Pharmacy II, 81 FR 31,310, 31,340 n.68 (2016); *see Hatem M. Ataya, M.D.,* 81 FR 8221, 8224 (2016). Alternatively, an applicant may rebut the Government's *prima facie* case for denial of the application by accepting responsibility for wrongful behavior and by taking remedial measures to ''prevent the re-occurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010). When assessing the appropriateness and extent of sanctioning, the DEA considers the egregiousness of an applicant's offenses and the DEA's interest in specific and general deterrence. *David A. Ruben, M.D.,* 78 FR 38,363, 38,385 (2013).

In this case, the Government alleged that Dr. Daniels materially falsified his application for a Certificate of Registration by failing to disclose a restriction on his Louisiana state controlled substance license that was imposed on him by a Consent Order issued by the Louisiana Medical Board, *[which would constitute a ground for revocation or denial of an application under 21 U.S.C. 824(a)(1). *See Robert Wayne Locklear, M.D.,* 86 FR at 33,744–45 (collecting cases) (DEA has consistently used the grounds for revocation in section 824 as a basis for denial of an application)]. The Government also alleges that Factors Two and Four of the public interest standard set forth in 21 U.S.C. 823(f) weigh against the Respondent's registration. *See* ALJ–18. Additionally, evidence introduced by the Respondent merits consideration under Factor One.

I. The Government's Position

The Government presented its position in an opening statement, Tr. 16–19, and in its Post-Hearing Brief, which it submitted on January 10, 2020.[13] I have read and considered the Government's opening statement, and its Brief, in preparing this Recommended Decision. In its Brief, the Government's proposed findings of fact are essentially the same as the Findings of Fact set forth in this Recommended Decision. ALJ–18, at 4–22. The Findings of Fact in this Recommended Decision differ from those proposed by the Government, where I have found the Government's proposed findings to be in error or not relevant to resolve the issues in this case. [Omitted] *[I][14]

With respect to the public interest considerations, the Government argues that it is relying ''on the testimony of Dr. Kennedy to show that [Dr. Daniels] issued prescriptions . . . outside the usual course of professional practice, beneath the standard of care in the State of Louisiana, . . . and without a legitimate purpose.'' ALJ–18, at 29. The Government noted that Dr. Kennedy's opinion was informed by numerous Louisiana Regulations. *Id.* Informed by those regulations, Dr. Kennedy testified that the standard of care in Louisiana for the treatment of addiction patients requires that a physician: Conduct an adequate physical examination; obtain an adequate medical history through past medical records or the PMP; create a treatment plan that includes a rationale for treatment; maintain adequate treatment records; conduct urine drug screening; and document the response to abnormal screenings within the patient's medical record. *Id.* at 30. The Government also noted that Dr. Daniels did not dispute Dr. Kennedy's testimony concerning the standard of care. *Id.* at 30–31.

The Government argues that I should not credit the testimony of Dr. Daniels, or his witness LW. ALJ–18, at 31–35. It also argues that Dr. Daniels' evidence concerning the Clinic's use of PMP reports is ''demonstrably false.'' *Id.* at 35. I note that I have addressed the credibility of both Dr. Daniels and LW earlier in this Recommended Decision. Concerning the PMP reports, Government Exhibit 30 demonstrates that the Clinic viewed the PMP concerning only two of the eight patients identified in the Order to Show Cause. *See* FF 26. Nevertheless, that same exhibit shows that between June 18, 2016, and September 20, 2017, Dr. Daniels checked the PMP 497 times. GE–30.

Next, the Government summarized the evidence it presented with respect to each allegation contained in the Order to Show Cause, and argued it had proven its *prima facie* case for denial of Dr. Daniels' application. ALJ–18, at 36–40. Finally, the Government argues that Dr. Daniels has not accepted responsibility, and, thus, his application should be denied. *Id.* at 40–41.

II. The Respondent's Position

Dr. Daniels presented his position in an opening statement, Tr. 20–22, and in his Post-hearing Brief, which he submitted on January 10, 2020.[15] I have read and considered Dr. Daniels' opening statement, and his Brief, in preparing this Recommended Decision. In his Brief, Dr. Daniels' proposed findings of fact are essentially the same as the Findings of Fact set forth in this Recommended Decision. ALJ–19, at 3–21. The Findings of Fact in this Recommended Decision differ from those proposed by the Respondent, where I have found the Respondent's proposed findings to be in error or not relevant to resolve the issues in this case.

Regarding the allegation of material falsification, Dr. Daniels points out that when submitting his application he ''specifically referenced the Consent Order issued by the [California Board of Medicine] as further explanation of the suspension.'' *Id.* at 3. He also notes that the Government acknowledged that his affirmative answer to the liability question and his reference to the Consent Order in his application ''certainly put the DEA on notice to investigate the application and not to summarily approve it.'' *Id.*

With respect to whether his registration would be inconsistent with the public interest, Dr. Daniels argues that the ''case must rest on the question of whether [he] knowingly prescribed drugs for other than a medical purpose, and not whether [he] used good judgment or bad judgment in trying to actually treat a patient.'' *Id.* at 4. Dr. Daniels also calls into question the lack of Louisiana specific experience of the Government's expert, as well as the ''miniscule sampling of six charts,'' when compared to the number of patients he had treated at the Clinic. *Id.* at 4–5.

Dr. Daniels notes that the Government's expert testified that the standard of care requires that the treating physician: 1. Obtain a history from the patient; 2. Conduct a physical examination of the patient; 3. Obtain the patient's past medical records and review the patient's PMP; 4. Conduct drug screening of the patient; and 5. Develop a treatment plan for the patient. *Id.* at 5. Dr. Daniels then proceeds to review the evidence, patient by patient, arguing that ''the treatment provided by [him] to each of the subject patients met this test.'' *Id.* at 6. Dr. Daniels does acknowledge that ''[r]egarding the patient charts . . . some information was missing.'' *Id.* With respect to reviewing the patient's PMP, Dr. Daniels noted that ''Dr. Kennedy testified that prescription monitoring as an accepted practice requirement became effective in 2018. (Trans., pg. 393). The charts reviewed were for patient visits between 2016 thru 2017 when prescription

[13] The Government's Brief has been marked as ALJ–18.

[*I] I am omitting the paragraph where the ALJ discussed the Government's position on the material falsification charge, because the Government abandoned its allegations related to material falsification in its Exceptions, and therefore, I find that this issue is no longer relevant. *See also infra* III.

[14] [Footnote omitted. *See* n.I.]

[15] Respondent's post-hearing brief has been marked as ALJ–19.

monitoring was more of a recommendation.'' *Id.* at 8.

Dr. Daniels argued that when presented with the results of an abnormal urine drug screen, ''he reacted to the information with directives for his staff to carry out.'' *Id.* Dr. Daniels states that ''[c]ounseling to the patient was always appropriate.'' *Id.* Furthermore, the Patient Treatment Agreements required drug screening as part of the recovery plan. *Id.* Dr. Daniels than addressed each of the subject patients, essentially reviewing their case files as he did when he testified. *Id.* at 9–21. For each patient, except JW and TC, Dr. Daniels argues that the Government had presented no evidence suggesting that the patients were somehow engaged in diversion.[16] *Id.* at 11, 13, 15, 16, 17, 19.

In conclusion, Dr. Daniels acknowledges that ''the patient files needed much improvement.'' *Id.* at 22. He adds, however, that ''poor documentation is not evidence that prescriptions were written for illegitimate purposes.'' *Id.* Of note, Dr. Daniels does not address acceptance of responsibility or remedial steps he may have taken.

III. Material Falsification

The DEA alleged that on March 12, 2018, the Louisiana State Board of Medical Examiners (''the Board'') issued a Consent Order that ''imposed a continuing restriction on [Dr. Daniels'] ability to practice medicine and to prescribe controlled substances for pain management or addiction treatment.'' ALJ–1, at 3–4, para. 8(c). The DEA further alleged that Dr. Daniels' application for a DEA certificate of registration, dated March 16, 2018, failed to disclose the restriction imposed by the Board's Consent Order on his Louisiana state controlled substance license. *Id.* at 3–4, paras. 8–9. *[I am omitting the RD's discussion of material falsification,[17] [18] because the Government in its Exceptions abandoned the allegation. *See* Government Exceptions, at 1 (stating that the Government does not ''take exception to the ALJ's finding that Respondent did not materially falsify his DEA COR application.''). Accordingly, I am not including an analysis of whether the facts here would have amounted to a material falsification, but instead, I am removing the RD's legal analysis per the Government's request for me to ''decline to adopt those limited portions of the Recommended Decision.'' *Id.* at 8. I find, as did the ALJ, that there is more than enough support in the record without the material falsification allegations that Dr. Daniels' registration is inconsistent with the public interest and that the appropriate sanction is denial of his application, as further explained below.]

IV. Public Interest Factor One: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority

*[In determining the public interest, the ''recommendation of the appropriate State licensing board or professional disciplinary authority . . . shall be considered.'' 21 U.S.C. 823(f)(1). Two forms of recommendations appear in Agency decisions: (1) A recommendation to DEA directly from a state licensing board or professional disciplinary authority (hereinafter, appropriate state entity), which explicitly addresses the granting or retention of a DEA COR; and (2) the appropriate state entity's action regarding the licensure under its jurisdiction on the same matter that is the basis for the DEA OSC. *John O. Dimowo, M.D.,* 85 FR 15,800, 15,810 (2020); *see also Vincent J. Scolaro, D.O.,* 67 FR 42,060, 42,065 (2002).]

In this case, it is undisputed that Dr. Daniels holds a valid state medical license in Louisiana. Tr. 476; Stip. 1; GE–3. However, possession of a state license does not entitle a holder of that license to a DEA registration. *Mark De La Lama, P.A.,* 76 FR 20,011, 20,018 (2011). It is well established that a ''state license is a necessary, but not a sufficient condition for registration.'' *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003). The ultimate responsibility to determine whether a DEA registration is consistent with the public interest resides exclusively with the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 FR 6580, 6590 (2007), *aff'd Chien* v. *DEA,* 533 F.3d 828 (DC Cir. 2008).*[J]

The record contains no evidence of a recommendation *[to the Agency regarding whether or not Dr. Daniels' DEA controlled substance registration application should be granted] by a relevant state licensing board or professional disciplinary authority. *[*See John O. Dimowo, M.D.,* 85 FR 15,810. However, as previously discussed, the State Board issued Consent Order for Reprimand, which was reached following a notice of Summary Suspension in Part of Dr. Daniels' Medical License filed by the Louisiana State Board of Medical Examiners (the Board) against Dr. Daniels based on ''information that he prescribed controlled substances without sufficient documentation.'' GE–5 and RE–1 (Consent Order); GE–2 (Summary Suspension). Neither the Consent Order, nor the Summary Suspension Order details the allegations against Dr. Daniels, so it is difficult to determine whether the State Board considered the same allegations and the extent of violations that DEA is considering herein. However, the Consent Order states that ''Dr. Daniels has surrendered his controlled dangerous substance registration to federal authorities.'' GE–5, at 1. Therefore, at the time the Board made its decision, Dr. Daniels was without a DEA registration and the Board had no reason to know whether he would receive one again. The Consent Order also included restrictions, which were proposed by Dr. Daniels, on Dr. Daniels' ability ''to prescribe controlled substances for chronic pain or obesity, associating himself with a drug treatment clinic, or serving in any position of responsibility for the health care services provided by others.'' *Id.* at 1–2. Therefore, the Consent Order does not indicate that the Board has a substantial amount of trust in Dr. Daniels' prescribing. For all of these reasons, the terms of the Board's Consent Order are not dispositive of the public interest inquiry in this case, and although I have considered it slightly in favor of Respondent, it is also minimized by the circumstances described above. *See John O. Dimowo,* 85 FR 15,810–11 (citing *Brian Thomas Nichol, M.D.,* 83 FR 47,352, 47,362–63 (2018)).] *[K]

[16] The Government, however, is not required to prove that diversion resulted from the unauthorized issuance of prescriptions. *Arvinder Singh, M.D.,* 81 FR 8247, 8249 (2016) *[(parentheticals omitted). In fact, Agency decisions have made clear 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 his obligations under the CSA and Louisiana law. *See George Mathew, M.D.,* 75 FR 66,138, 66,148 (2010).].

[17] [Footnote omitted regarding material falsification.]

[18] [Footnote omitted regarding material falsification.]

*[J] I moved the three sentences preceding this footnote from the RD to provide further analysis of Factor 1 in accordance with Agency decisions.

*[K] It is noted that the ALJ found that this Factor weighed neither for nor against Dr. Daniels. *See* RD, at 69. Although I am weighing the factor slightly in his favor, it does not outweigh the egregious violations of law and misconduct in prescribing that I am considering under Factors 2 and 4.

V. Public Interest Factors Two & Four: The Respondent's Experience in Dispensing Controlled Substances and Compliance with Applicable State, Federal, or Local Laws Relating to Controlled Substances

[*L] [ ] Here, the Government alleges that denying Dr. Daniels' COR application is appropriate under Factors Two and Four because Dr. Daniels improperly prescribed controlled substances to: Six addiction treatment patients; a pain patient; and an undercover patient. ALJ–1, at 4–8, paras. 10–19.

It is unlawful for a practitioner to distribute controlled substances except as authorized under the CSA. 21 U.S.C. 841(a)(1). To combat abuse and diversion of controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.'' *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). To maintain this closed regulatory system, a DEA registrant may prescribe a controlled substance only by writing a valid prescription. *Carlos Gonzalez, M.D.,* 76 FR 63,118, 63,141 (2011). As the Supreme Court explained, ''the prescription requirement . . . ensures that patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. at 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135, 143 (1975)). * [According to the CSA's implementing regulations, a lawful] controlled substance prescription is valid only when it 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). Federal regulations further provide that ''[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it[ ] shall be subject to the penalties provided for violations of [controlled substance laws].'' *Id.* Furthermore, 21 U.S.C. 842(a)(1) establishes that it is illegal for a person to distribute or dispense controlled substances without a prescription, as is required under 21 U.S.C. 829. [ ][*M]

The Government presented the expert testimony of Dr. Kennedy, who testified that Dr. Daniels' prescriptions to the patients in this case were not issued for legitimate medical purposes and were issued outside the usual course of professional practice. Second, the Government has shown through the testimony of its expert witness that Dr. Daniels violated the Louisiana standard of care *[and Louisiana law]. [ ][*N]

[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.' '' *Mark A. Wimbley, M.D.,* 86 FR 20,713, 20,726 (2021) (quoting *Cynthia M. Cadet, M.D.,* 76 FR 19,450, 19,464 (2011)); *[*see also Kaniz F. Khan-Jaffery, M.D.,* 85 FR 45,667, 45,686 (2020) (''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.''). Here, Respondent's sparse documentation made it impossible to evaluate his prescribing practices in any meaningful way.]

In fact, several of the regulatory provisions cited by the Government and Dr. Kennedy impose specific requirements on practitioners when practitioners obtain evidence that a patient is abusing or diverting controlled substances. In addition, Louisiana's controlled substance regulations also require practitioners to conduct urine drug screens and check the PMP, precautionary actions designed to check for abuse and diversion.

Because Dr. Daniels practices medicine in Louisiana, and because the OSC cites to specific provisions of Louisiana law and regulations, it is important to review the requirements of Louisiana law as they relate to professional conduct and the maintenance of medical records.

Louisiana Law

Louisiana law imposes requirements on controlled substance prescriptions similar to those imposed by the Controlled Substances Act and its implementing regulations. For example, under Louisiana law, ''[a] prescription for a controlled substance shall be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1). Louisiana law further provides that ''[a]n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Controlled Substances Act.'' *Id.*

Louisiana law provides that treating chronic pain not related to cancer with controlled substances ''constitutes legitimate medical therapy when provided in the course of professional medical practice and when fully documented in the patient's medical record.'' La. Admin. Code tit. 46, Pt. XLV, § 6919. Louisiana law imposes several limitations on the use of controlled substances in the medical treatment of non-cancer related chronic pain. Specifically, Louisiana law requires that the medical practitioner evaluate the patient; diagnose the patient; establish a treatment plan; and obtain informed consent. *Id.* at § 6921(A)(1)–(4).

To comply with Louisiana law, a medical evaluation must include ''relevant medical, pain, alcohol and substance abuse histories''; assessment of the pain's impact ''on the patient's physical and psychological functions''; review of past diagnostic tests; previously utilized therapies; ''assessment of coexisting illnesses, diseases, or conditions''; and ''an appropriate physical examination.'' *Id.* at § 6921(A)(1).

With respect to the requirement to diagnose the patient, Louisiana law provides that ''[a] medical diagnosis shall be established and fully documented in the patient's medical record.'' *Id.* at § 6921(A)(2). The patient's medical record must indicate ''the presence of noncancer-related chronic or intractable pain'' and ''the nature of the underlying disease and pain mechanism,'' if possible for the practitioner to determine. *Id.*

In addition to the requirement to document a diagnosis, Louisiana law also requires the practitioner to document in the patient's medical record a treatment plan that provides medical justification for the use of controlled substances. *Id.* at § 6921(A)(3). The treatment plan must be tailored to each patient's individual needs. *Id.* The treatment plan must also ''include documentation that other medically reasonable alternative treatments for relief of the patient's noncancer-related chronic or intractable pain have been considered or attempted without adequate or reasonable success.'' *Id.* In addition, the treatment plan must ''specify the intended role of

[*L] Omitted content for clarity.

[*M] I am omitting some of the ALJ's analysis related to 21 CFR 1306.04(a) for brevity and clarity.

[*N] Omitted. *See* supra n.M

controlled substance therapy within the overall plan.'' *Id.*

Lastly, with respect to informed consent, Louisiana law requires the practitioner to ensure the patient is informed of the risks and benefits of controlled substance therapy. *Id.* at § 6921(A)(4). Louisiana law requires that ''[d]iscussions of risks and benefits should be noted in some format in the patient's record.'' *Id.*

Once a practitioner determines that controlled substance therapy is justified, Louisiana law imposes several additional requirements, to include the requirement that the practitioner: Monitor and assess the treatment's efficacy; conduct urine drug screens if appropriate; assume primary responsibility for the patient's controlled substance therapy; refer the patient for further evaluation and treatment if necessary; document the need for prescribing more than one controlled substance; maintain complete and accurate medical records; and document specific information concerning the controlled substance therapy. *Id.* at § 6921(B)(1)–(7).

Specifically, the practitioner must see the patient ''at appropriate intervals, not to exceed 12 weeks, to assess the efficacy of treatment, assure that controlled substance therapy remains indicated, and evaluate the patient's progress toward treatment objectives and any adverse drug effects.'' *Id.* at § 6921(B)(1). The requirement to monitor and assess the efficacy of controlled substance therapy includes the requirement to evaluate any ''[i]ndications of substance abuse or diversion.'' *Id.* In addition, the practitioner ''should seek evidence of under treatment of pain'' and assess ''the possibility of decreased function or quality of life as a result of controlled substance treatment.'' *Id.*

With respect to urine drug screens, Louisiana law requires that if the practitioner ''reasonably believes'' the patient is abusing or diverting controlled substances, the practitioner ''shall obtain a urine drug screen on the patient.'' *Id.* at § 6921(B)(2). In addition, Louisiana law requires that ''[a] single physician shall take primary responsibility'' for a patient's controlled substance therapy. *Id.* at § 6921(B)(3).

In addition, a practitioner treating a patient with controlled substances ''should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.'' *Id.* at § 6921(B)(4). Using controlled substances to treat patients with a history of substance abuse or with psychiatric disorders ''may require extra care, monitoring, documentation, and consultation with or referral to an expert.'' *Id.* Louisiana law specifically instructs practitioners to pay special attention to patients who are at-risk for misusing or diverting their controlled substances. *Id.*

Louisiana law also requires that if a practitioner prescribes more than one controlled substance to a patient, the practitioner must ''document in the patient's medical record the medical necessity for the use of more than one type or schedule of controlled substance.'' *Id.* at § 6921(B)(5).

Furthermore, Louisiana law imposes several specific requirements concerning the information that a practitioner must document in a patient's medical record. Specifically, Louisiana law provides that with respect to medical records:

> A physician shall document and maintain in the patient's medical record, accurate and complete records of history, physical and other examinations and evaluations, consultations, laboratory and diagnostic reports, treatment plans and objectives, controlled substance and other medication therapy, informed consents, periodic assessments, and reviews and the results of all other attempts at analgesia which he has employed alternative to controlled substance therapy.

Id. at § 6921(B)(6).

With respect to controlled substance prescriptions, a Louisiana practitioner must also document in the patient's medical record: ''The date, quantity, dosage, route, frequency of administration, the number of controlled substance refills authorized, as well as the frequency of visits to obtain refills.'' *Id.* at § 6921(B)(7).

Louisiana law also provides that if a practitioner obtains evidence of, or if a patient's behavior indicates, abuse or diversion of controlled substances, the practitioner should taper the patient's prescriptions and discontinue controlled substance therapy. *Id.* at § 6921(C). The practitioner should only reinitiate controlled substance therapy after an addiction or pain management specialist, or psychiatrist, provides written support for ''the medical necessity of continued controlled substance therapy.'' *Id.*

Louisiana law also imposes requirements on behavioral health service providers, which includes practitioners who provide substance abuse or addiction treatment services. La. Admin. Code tit. 48, Pt. I, § 5603. Among those requirements include the requirement to maintain a client record ''according to current professional standards'' and to ensure medical records contain, at minimum, the treatment provided to the patient; the patient's response to treatment; initial assessment, diagnosis, and referral information; treatment plan; results of diagnostic and laboratory tests; and progress notes. *Id.* at § 5637(A)–(B). In addition, a practitioner must document in the patient's medical record the results of the patient's five most recent urine drug screens, as well as the action the practitioner took ''for positive results.'' *Id.* at § 5731(A)(2). Providers operating an opioid treatment program must ''conduct at least eight random monthly drug screen tests on each'' patient per year. *Id.* at § 5723(A)(4).

Behavioral Health Service [*O] providers must also conduct an initial assessment of a patient admitted for behavioral health services, to include a physical examination and drug screening. *Id.* at § 5647(C)(4)(b)–(c). In addition, the initial assessment must also contain a biopsycho-social evaluation, which covers, among other information, the reason for the patient's admission to behavioral health services; medical history and past treatment; family and social history; living situation; education level; employment status; and functioning level. *Id.* at § 5647(C)(4)(b). A practitioner may only admit a patient to behavioral health services if the practitioner has verified that ''treatment is medically necessary,'' and if the patient has had a complete physical evaluation before admission, and a full medical examination within 14 days of admission. *Id.* at § 5725(A)(3)–(5).[*P]

[*O] I made a slight correction here to the RD, because the regulation appears to apply to all Behavioral Health Service providers, including outpatient substance abuse or addiction treatment service providers, such as the Clinic where Dr. Daniels worked at the time of the allegations. I find that the substantial record evidence supports a finding that the Clinic was a Behavioral Health Service provider and that, therefore, these provisions of Louisiana regulations apply. Tr. 126, 421; La. Admin. Code tit. 48, Pt. I, § 5603 (defining a Behavioral Health Service provider as a clinic that ''provides behavioral health services, presents itself to the public as a *provider* of behavioral health services.'')

[*P] In this case, the requirement to adequately address and document aberrant results of the urine drug screens has been fully established by Louisiana law and the standard of care as testified to by Dr. Kennedy, whose expert testimony is unrebutted. *See* La. Admin. Code tit. 48, Pt. I, § 5731(A)(2). As discussed herein, Dr. Kennedy testified that many of the urine drug screens were aberrant and there was no documentation of their resolution in violation of state regulations and the usual course of professional practice. *See infra* AK, CA, MN, JD, SB, and CM. The ALJ added a section in the RD here regarding other DEA decisions that considered a practitioner's failure to address aberrant urine drug screens in assessing whether a registration was inconsistent with the public interest. *See Hatem M. Ataya, M.D.,* 81 FR 8221, 8227 (2016); *Jacobo Dreszer, M.D.,* 76 FR at 19,388, 19,394 (2011); ''[A] practitioner's failure to properly

Addiction Treatment

The Government alleged that between May 2016 and September 2017, Dr. Daniels prescribed controlled substances to patients AK, CA, MN, JD, SB, and CM, outside the usual course of professional practice and not for legitimate medical purposes, in violation of federal and state law. ALJ–1, at 4, paras. 10–12. Specifically, the Government alleged that Dr. Daniels' prescriptions to these patients exhibited several deficiencies, to include Dr. Daniels' failure to conduct physical examinations; failure to request the patients' past medical records; failure to obtain PMP reports; failure to resolve aberrant urine drug screens; and failure to document the rationale for his medical treatment. ALJ–1, at 5, para. 12(a)–(e).

In addition, the Government alleged that Dr. Daniels prescribed patients AK, CA, MN, SB, and CM, prescriptions for both buprenorphine (Subutex) and clonazepam. The Government further alleged that both of these controlled substances were respiratory depressants, and that Dr. Daniels failed to document in the patients' medical records any rationale that justified prescribing buprenorphine and clonazepam at the same time. ALJ–1, at 5, para. 13. Dr. Daniels also failed to document in the patients' medical records that he discussed with them the risks of taking these controlled substances at the same time. *Id.*

During his testimony, Dr. Kennedy provided guidance concerning the standard of care in Louisiana. For example, to prescribe controlled substances in Louisiana for the treatment of chemical dependency, the standard of care requires the treating physician to: Conduct an adequate physical examination; obtain past medical records; obtain PMP reports; conduct drug screening; and maintain medical records. FF 46. In addition, the standard of care requires that a patient's medical record be ''complete and accurate.'' FF 47. With respect to the Louisiana PMP, prior to 2018, doctors in Louisiana were not required to check a patient's PMP before writing a prescription for a controlled substance, but it was considered the standard of care. FF 65.

Patient AK

The Government alleged that all of the prescriptions for controlled substances that Dr. Daniels issued to Patient AK, between May 2016 and September 2017,[19] were issued outside the usual course of professional practice and not for legitimate medical purposes, in violation of federal and state law. ALJ–1, at 4–5, paras. 12–13. With respect to AK, the Government alleged that the prescriptions were issued outside the usual course of professional practice and not for legitimate medical purposes for the following five reasons. First, Dr. Daniels failed to conduct a physical examination of AK, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Second, Dr. Daniels failed to request AK's medical records concerning prior substance abuse or past treatment of substance abuse, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Third, Dr. Daniels failed to obtain a report from the Louisiana Prescription Monitoring Program for AK, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Fourth, Dr. Daniels failed to address in AK's medical record the results of abnormal urine drug screens, to include results that were positive for illicit substances and negative for substances that Dr. Daniels prescribed, as required by La. Admin. Code tit. 48, Pt. I, §§ 5723, 5725, 5731. And fifth, Dr. Daniels failed to document in AK's medical records his rationale for his medical treatment of AK, to include his reason for initiating buprenorphine treatment at high dosages, as required by La. Admin. Code tit. 48, Pt. I, §§ 5637, 5731. ALJ–1, at 5, para. 12(a)–(e).

In addition, the Government alleged that Dr. Daniels issued prescriptions for both buprenorphine and Klonopin to AK at the same time. Because Dr. Daniels failed to document in AK's medical record any rationale that justified prescribing buprenorphine and clonazepam at the same time, and because Dr. Daniels failed to document that he discussed with AK the risks of taking these controlled substances at the same time, the prescriptions were beneath the standard of care for the practice of medicine in Louisiana, outside the usual course of professional practice, and not for a legitimate medical purpose. ALJ–1, at 5–6, paras. 13–15.

During the hearing the Government established by a preponderance of the evidence that Dr. Daniels did not perform, or he failed to document that he performed a physical examination of AK. FF 78, 82, 83, 91, 92, 94, 97. Dr. Daniels also failed to obtain past medical records concerning AK. FF 76, 92, 97; Tr. 198. Although the standard of care dictated that Dr. Daniels check AK's PMP, he did not do so. FF 26, 85, 92, 97. Although Dr. Daniels did conduct some urine drug screens of AK, there is no documentation of any action he may have taken concerning screenings that were abnormal. FF 86, 87, 92, 94, 97. Finally, Dr. Daniels did not document within AK's medical record a rationale for the controlled substances he prescribed to AK. FF 81, 94, 97. Accordingly, *[I find based on the unrebutted, credible testimony of Dr. Kennedy, and as supported by the evidence] that the prescriptions that Dr. Daniels issued to AK were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 97.

While the preponderance of the Government's evidence establishes that the medical records Dr. Daniels maintained on AK, failed to provide an adequate justification for Klonopin, it did not establish the dangers of prescribing buprenorphine and Klonopin together, or that Dr. Daniels failed to caution AK of the dangers. FF 70. In fact, the Government presented no evidence that both buprenorphine and Klonopin are respiratory depressants. In addition, AK's medical records include a Patient Treatment Contract that AK signed that specifically warned AK of the dangers of taking buprenorphine and Klonopin together. FF 72. Nevertheless, the Government established by a preponderance of the evidence that, for a number of reasons, all of the prescriptions identified in Stipulation 17 were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 97.

Accordingly, the allegations contained in Paragraph 12 of the Order to Show Cause that Dr. Daniels issued

supervise his patients to prevent them from personally abusing controlled substances or selling them to others constitutes conduct 'inconsistent with the public interest' and can support the denial of an application for registration, or the revocation of an existing registration.'' *Bienvenido Tan, M.D.,* 76 FR 17,673, 17,689 (2011) (quoting *Paul J. Caragine, Jr.,* 63 FR 51,592, 51,601 (1998)); *Mireille Lalanne, M.D.,* 78 FR 47,750, 47,766–68 (2013) (finding that failing to confront a patient about inconsistent drug screens by itself is sufficient evidence to show that the registrant acted outside the scope of professional practice). I have omitted this section of the RD, but included some of the cited decisions herein. *See Kaniz Khan-Jaffery,* 85 FR 45,667, n.71 (2020) (''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.'') It is noted that, the decisions cited in the RD and this footnote, relied on expertise regarding the applicable standard of care and usual course of professional practice to those particular registrants, as does this decision.

[19] This includes all of the prescriptions listed in Stipulation 17.

prescriptions to Patient AK in violation of La. Admin. Code tit. 48, Pt. I, §§ 5637, 5647, 5723, 5725, 5731 are SUSTAINED. Because the Government presented no evidence that established that buprenorphine and Klonopin (clonazepam) are respiratory depressants, and because the number of prescriptions alleged in the Order to Show Cause to have been issued by Dr. Daniels to AK is inconsistent with the Government's proof, the allegations contained in Paragraphs 13–15 of the Order to Show Cause concerning AK are NOT SUSTAINED. Nevertheless, by sustaining the allegations contained in Paragraph 12, I have found that all of the prescriptions that Dr. Daniels wrote for AK, including those for buprenorphine and Klonopin, identified in Stipulation 17, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. These violations weigh in favor of denying Dr. Daniels' pending application for a Certificate of Registration.

Patient CA

The Government alleged that all of the prescriptions for controlled substances that Dr. Daniels issued to Patient CA, between May 2016 and September 2017,[20] were issued outside the usual course of professional practice and not for legitimate medical purposes, in violation of federal and state law. ALJ–1, at 4–5, paras. 12–13. With respect to CA, the Government alleged that the prescriptions were issued outside the usual course of professional practice and not for legitimate medical purposes for the following five reasons. First, Dr. Daniels failed to conduct a physical examination of CA, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Second, Dr. Daniels failed to request CA's medical records concerning prior substance abuse or past treatment of substance abuse, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Third, Dr. Daniels failed to obtain a report from the Louisiana Prescription Monitoring Program for CA, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Fourth, Dr. Daniels failed to address in CA's medical record the results of abnormal urine drug screens, to include results that were positive for illicit substances and negative for substances that Dr. Daniels prescribed, as required by La. Admin. Code tit. 48, Pt. I, §§ 5723, 5725, 5731. And fifth, Dr. Daniels failed to document in CA's medical records his rationale for his medical treatment of CA, to include his reason for initiating buprenorphine treatment at high dosages, as required by La. Admin. Code tit. 48, Pt. I, §§ 5637, 5731. ALJ–1, at 5, para. 12(a)–(e).

In addition, the Government alleged that Dr. Daniels issued prescriptions for both buprenorphine and Klonopin to CA at the same time. Because Dr. Daniels failed to document in CA's medical record a rationale for prescribing buprenorphine and clonazepam at the same time, and because Dr. Daniels failed to document that he discussed with CA the risks of taking these controlled substances at the same time, the prescriptions were beneath the standard of care for the practice of medicine in Louisiana, outside the usual course of professional practice, and not for a legitimate medical purpose. ALJ–1, at 5–6, paras. 13–15. The Government also alleged that Dr. Daniels failed to document any rationale for prescribing Adderall to CA. ALJ–1, at 6, para. 14.b.i.

During the hearing the Government established by a preponderance of the evidence that Dr. Daniels did not perform, or he failed to document that he performed a physical examination of CA. FF 103, 107, 109, 110, 118. Dr. Daniels also failed to obtain past medical records concerning CA. FF 105; Tr. 198. The evidence shows, however, that Dr. Daniels checked CA's PMP, but he did not do so until more than a year after he first prescribed controlled substances to CA. FF 26. Although Dr. Daniels did conduct some urine drug screens of CA, there is no documentation of any action he may have taken concerning screenings that were abnormal. FF 101, 102, 111–13, 115–17, 119. Finally, Dr. Daniels did not document within CA's medical record a rationale for the controlled substances he prescribed to CA. FF 103, 108–10, 118. Accordingly, *[I find, based on the unrebutted, credible, expert testimony of Dr. Kennedy, and as supported by the evidence] that the prescriptions that Dr. Daniels issued to CA were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 121.

While the preponderance of the Government's evidence establishes that the medical records Dr. Daniels maintained on CA failed to provide an adequate justification for Klonopin, it did not establish the dangers of prescribing buprenorphine and Klonopin together, or that Dr. Daniels failed to caution CA of the dangers. FF 70. In fact, the Government presented no evidence that both buprenorphine and Klonopin are respiratory depressants. In addition, CA's medical records include a Patient Treatment Contract that CA signed that specifically warned CA of the dangers of taking buprenorphine and Klonopin together. FF 99. *[Additionally, both Dr. Daniels and Dr. Kennedy testified that prescribing both Klonopin and buprenorphine is not outside the usual course of professional practice. Tr. 315, 518.] Nevertheless, the Government established by a preponderance of the evidence that, for a number of reasons, all of the prescriptions identified in Stipulation 22, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 121. With respect to the prescriptions for Adderall that Dr. Daniels prescribed to CA, the Government established Dr. Daniels did not document a rationale for prescribing Adderall to CA. FF 103. In fact, during his testimony, Dr. Daniels acknowledged that the justification was not contained in CA's medical records. FF 108.

Accordingly, the allegations contained in Paragraph 12 of the Order to Show Cause that Dr. Daniels issued prescriptions to Patient CA in violation of La. Admin. Code tit. 48, Pt. I, §§ 5637, 5647, 5723, 5725, 5731 are SUSTAINED. Because the Government presented no evidence that established that buprenorphine and Klonopin (clonazepam) are respiratory depressants, and because the number of prescriptions alleged in the Order to Show Cause to have been issued by Dr. Daniels to CA is inconsistent with the Government's proof, the allegations contained in Paragraphs 13–15 of the Order to Show Cause concerning CA are NOT SUSTAINED. Nevertheless, by sustaining the allegations contained in Paragraph 12, I have found that all of the prescriptions that Dr. Daniels wrote for CA, identified in Stipulation 22, including those for buprenorphine and Klonopin, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. Furthermore, the allegation contained in ALJ–1, at 6, para. 14.b.i., that Dr. Daniels failed to document a rationale for prescribing Adderall to CA is not documented in CA's medical record in violation of 21 U.S.C. 841(a) and 842(a); 21 CFR 1304.04(a); and La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1), is SUSTAINED. These violations weigh in favor of denying Dr. Daniels' pending application for a Certificate of Registration.

Patient MN

The Government alleged that all of the prescriptions for controlled substances

[20] This includes all of the prescriptions listed in Stipulation 22.

that Dr. Daniels issued to Patient MN, between May 2016 and September 2017,[21] were issued outside the usual course of professional practice and not for legitimate medical purposes, in violation of federal and state law. ALJ–1, at 4–5, paras. 12–13. With respect to MN, the Government alleged that the prescriptions were issued outside the usual course of professional practice and not for legitimate medical purposes for the following five reasons. First, Dr. Daniels failed to conduct a physical examination of MN, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Second, Dr. Daniels failed to request MN's medical records concerning prior substance abuse or past treatment of substance abuse, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Third, Dr. Daniels failed to obtain a report from the Louisiana Prescription Monitoring Program for MN, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Fourth, Dr. Daniels failed to address in MN's medical record the results of abnormal urine drug screens, to include results that were positive for illicit substances and negative for substances that Dr. Daniels prescribed, as required by La. Admin. Code tit. 48, Pt. I, §§ 5723, 5725, 5731. And fifth, Dr. Daniels failed to document in MN's medical records his rationale for his medical treatment of MN, to include his reason for initiating buprenorphine treatment at high dosages, as required by La. Admin. Code tit. 48, Pt. I, §§ 5637, 5731. ALJ–1, at 5, para. 12(a)–(e).

In addition, the Government alleged that Dr. Daniels issued prescriptions for both buprenorphine and Klonopin to MN at the same time. Because Dr. Daniels failed to document in the MN's medical record a rationale for prescribing buprenorphine and clonazepam at the same time, and because Dr. Daniels failed to document that he discussed with MN the risks of taking these controlled substances at the same time, the prescriptions were beneath the standard of care for the practice of medicine in Louisiana, outside the usual course of professional practice, and not for a legitimate medical purpose. ALJ–1, at 5–6, paras. 13–15.

During the hearing the Government established by a preponderance of the evidence that Dr. Daniels did not perform, or he failed to document that he performed, a physical examination of MN. FF 128–29, 136–37. Dr. Daniels also failed to obtain past medical records concerning MN. FF 137; Tr. 198. Although the standard of care dictated that Dr. Daniels check MN's PMP, he did not do so. FF 26, 137. Although Dr. Daniels did conduct some urine drug screens of MN, there is no documentation of any action he may have taken concerning screenings that were abnormal. FF 126–27, 132–33, 135, 137. Finally, Dr. Daniels did not document within MN's medical record a rationale for the controlled substances he prescribed to MN. FF 128, 137. Accordingly, *[I find based on the unrebutted, credible, expert testimony of Dr. Kennedy, and as supported by the evidence] that the prescriptions that Dr. Daniels issued to MN were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 137.

While the preponderance of the Government's evidence establishes that the medical records Dr. Daniels maintained on MN failed to provide an adequate justification for Klonopin, it did not establish the dangers of prescribing buprenorphine and Klonopin together, or that Dr. Daniels failed to caution MN of the dangers. FF 70. In fact, the Government presented no evidence that both buprenorphine and Klonopin are respiratory depressants. In addition, MN's medical records include a Patient Treatment Contract that MN signed that specifically warned MN of the dangers of taking buprenorphine and Klonopin together. FF 124. Nevertheless, the Government established by a preponderance of the evidence that, for a number of reasons, all of the prescriptions identified in Stipulation 24 were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 137.

Accordingly, the allegations contained in Paragraph 12 of the Order to Show Cause that Dr. Daniels issued prescriptions to Patient MN in violation of La. Admin. Code tit. 48, Pt. I, §§ 5637, 5647, 5723, 5725, 5731 are SUSTAINED. Because the Government presented no evidence that established that both buprenorphine and Klonopin (clonazepam) are respiratory depressants, the allegations contained in Paragraphs 13–15 of the Order to Show Cause concerning MN are NOT SUSTAINED. Nevertheless, by sustaining the allegations contained in Paragraph 12, I have found that all of the prescriptions that Dr. Daniels wrote for MN, including those for buprenorphine and Klonopin, identified in Stipulation 24, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. These violations weigh in favor of denying Dr. Daniels' pending application for a Certificate of Registration.

Patient JD

The Government alleged that all of the prescriptions for controlled substances that Dr. Daniels issued to Patient JD, between May 2016 and September 2017,[22] were issued outside the usual course of professional practice and not for legitimate medical purposes, in violation of federal and state law. ALJ–1, at 4–5, paras. 12–13. With respect to JD, the Government alleged that the prescriptions were issued outside the usual course of professional practice and not for legitimate medical purposes for the following five reasons. First, Dr. Daniels failed to conduct a physical examination of JD, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Second, Dr. Daniels failed to request JD's medical records concerning prior substance abuse or past treatment of substance abuse, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Third, Dr. Daniels failed to obtain a report from the Louisiana Prescription Monitoring Program for JD, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Fourth, Dr. Daniels failed to address in JD's medical record the results of abnormal urine drug screens, to include results that were positive for illicit substances and negative for substances that Dr. Daniels prescribed, as required by La. Admin. Code tit. 48, Pt. I, §§ 5723, 5725, 5731. And fifth, Dr. Daniels failed to document in JD's medical records his rationale for his medical treatment of JD, to include his reason for initiating buprenorphine treatment at high dosages, as required by La. Admin. Code tit. 48, Pt. I, §§ 5637, 5731. ALJ–1, at 5, para. 12(a)–(e).

During the hearing the Government established by a preponderance of the evidence that Dr. Daniels did not perform, or he failed to document that he performed a physical examination of JD. FF 143. Dr. Daniels also failed to obtain past medical records concerning JD. FF 143; Tr. 198. Although the standard of care dictated that Dr. Daniels check JD's PMP, he did not do so. FF 26. Although Dr. Daniels conducted a urine drug screen of JD, due to the length of time he treated JD, Dr. Daniels should have conducted additional urine drug screens of JD. FF 145; La. Admin. Code tit. 48, Pt. I § 5723(A)(4). Finally, Dr. Daniels did not document within JD's medical record a rationale for the controlled

[21] This includes all of the prescriptions listed in Stipulation 24.

[22] This includes all of the prescriptions listed in Stipulation 27.

substances he prescribed to JD. FF 177. Accordingly, I *[I find based on the unrebutted, credible, expert testimony of Dr. Kennedy, and as supported by the evidence] that the prescriptions that Dr. Daniels issued to JD were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 147. Of significance, Dr. Kennedy's opinion concerning the prescriptions that Dr. Daniels issued to JD was based on the fact that there was no documented follow-up care of JD after his initial visit with Dr. Daniels, though JD continued to obtain prescriptions from Dr. Daniels for more than a year after obtaining his first prescription from Dr. Daniels. FF 147; Stip. 27.

Accordingly, the allegations contained in Paragraph 12 of the Order to Show Cause that Dr. Daniels issued prescriptions to Patient JD in violation of La. Admin. Code tit. 48, Pt. I, §§ 5637, 5647, 5723, 5725, 5731 are SUSTAINED. These violations weigh in favor of denying Dr. Daniels' pending application for a Certificate of Registration.

Patient SB

The Government alleged that all of the prescriptions for controlled substances that Dr. Daniels issued to Patient SB, between May 2016 and September 2017,[23] were issued outside the usual course of professional practice and not for legitimate medical purposes, in violation of federal and state law. ALJ–1, at 4–5, paras. 12–13. With respect to SB, the Government alleged that the prescriptions were issued outside the usual course of professional practice and not for legitimate medical purposes for the following five reasons. First, Dr. Daniels failed to conduct a physical examination of SB, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725.

Second, Dr. Daniels failed to request SB's medical records concerning prior substance abuse or past treatment of substance abuse, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Third, Dr. Daniels failed to obtain a report from the Louisiana Prescription Monitoring Program for SB, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Fourth, Dr. Daniels failed to address in SB's medical record the results of abnormal urine drug screens, to include results that were positive for illicit substances and negative for substances that Dr. Daniels prescribed, as required by La. Admin. Code tit. 48, Pt. I, §§ 5723, 5725, 5731. And fifth, Dr. Daniels failed to document in SB's medical records his rationale for his medical treatment of SB, to include his reason for initiating buprenorphine treatment at high dosages, as required by La. Admin. Code tit. 48, Pt. I, §§ 5637, 5731. ALJ–1, at 5, para. 12(a)–(e).

In addition, the Government alleged that Dr. Daniels issued prescriptions for both buprenorphine and Klonopin to SB at the same time. Because Dr. Daniels failed to document in SB's medical record a rationale for prescribing buprenorphine and clonazepam at the same time, and because Dr. Daniels failed to document that he discussed the risks of taking these controlled substances at the same time with SB, the prescriptions were beneath the standard of care for the practice of medicine in Louisiana, outside the usual course of professional practice, and not for a legitimate medical purpose. ALJ–1, at 5–6, paras. 13–15.

During the hearing the Government established by a preponderance of the evidence that Dr. Daniels did not perform, or he failed to document that he performed, a physical examination of SB. FF 152, 156. Dr. Daniels also failed to obtain past medical records concerning SB. FF 153; Tr. 198. Although the standard of care dictated that Dr. Daniels check SB's PMP, he did not do so. FF 26. Although Dr. Daniels did conduct some urine drug screens of SB, there is no documentation of any action he may have taken concerning screenings that were abnormal. FF 154–55, 157. Finally, Dr. Daniels did not document within SB's medical record a rationale for the controlled substances he prescribed to SB. FF 152, 154, 157. Accordingly, *[I find based on the unrebutted, credible, expert testimony of Dr. Kennedy, and as supported by the evidence] that the prescriptions that Dr. Daniels issued to SB were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 157.

While the preponderance of the Government's evidence establishes that the medical records Dr. Daniels maintained on SB failed to provide an adequate justification for Klonopin, it did not establish the dangers of prescribing buprenorphine and Klonopin together, or that Dr. Daniels failed to caution SB of the dangers. FF 70. In fact, the Government presented no evidence that both buprenorphine and Klonopin are respiratory depressants. In addition, SB's medical records include a Patient Treatment Contract that SB signed that specifically warned SB of the dangers of taking buprenorphine and Klonopin together. FF 149. Nevertheless, the Government established by a preponderance of the evidence that, for a number of reasons, all of the prescriptions identified in Stipulation 29 were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 157.

Accordingly, the allegations contained in Paragraph 12 of the Order to Show Cause that Dr. Daniels issued prescriptions to Patient SB in violation of La. Admin. Code tit. 48, Pt. I, §§ 5637, 5647, 5723, 5725, 5731 are SUSTAINED. Because the Government presented no evidence that established that buprenorphine and Klonopin (clonazepam) are respiratory depressants the allegations contained in Paragraphs 13–15 of the Order to Show Cause concerning SB are NOT SUSTAINED. Nevertheless, by sustaining the allegations contained in Paragraph 12, I have found that all of the prescriptions that Dr. Daniels wrote for SB, including those for buprenorphine and Klonopin, identified in Stipulation 29, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. These violations weigh in favor of denying Dr. Daniels' pending application for a Certificate of Registration.

Patient CM

The Government alleged that all of the prescriptions for controlled substances that Dr. Daniels issued to Patient CM, between May 2016 and September 2017,[24] were issued outside the usual course of professional practice and not for legitimate medical purposes, in violation of federal and state law. ALJ–1, at 4–5, paras. 12–13. With respect to CM, the Government alleged that the prescriptions were issued outside the usual course of professional practice and not for legitimate medical purposes for the following five reasons. First, Dr. Daniels failed to conduct a physical examination of CM, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Second, Dr. Daniels failed to request CM's medical records concerning prior substance abuse or past treatment of substance abuse, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Third, Dr. Daniels failed to obtain a report from the Louisiana Prescription Monitoring Program for CM, as required by La. Admin. Code tit. 48, Pt. I, §§ 5647, 5725. Fourth, Dr. Daniels failed to address in CM's medical record the results of abnormal urine drug screens, to include results that were positive for illicit substances and negative for

[23] This includes all of the prescriptions listed in Stipulation 29.

[24] This includes all of the prescriptions listed in Stipulation 31.

substances that Dr. Daniels prescribed, as required by La. Admin. Code tit. 48, Pt. I, §§ 5723, 5725, 5731. And fifth, Dr. Daniels failed to document in CM's medical records his rationale for his medical treatment of CM, to include his reason for initiating buprenorphine treatment at high dosages, as required by La. Admin. Code tit. 48, Pt. I, §§ 5637, 5731. ALJ–1, at 5, para. 12(a)–(e).

In addition, the Government alleged that Dr. Daniels issued prescriptions for both buprenorphine and Klonopin to CM at the same time. Because Dr. Daniels failed to document in CM's medical record any rationale that justified prescribing buprenorphine and clonazepam at the same time, and because Dr. Daniels failed to document that he discussed with CM the risks of taking these controlled substances at the same time, the prescriptions were beneath the standard of care for the practice of medicine in Louisiana, outside the usual course of professional practice, and not for a legitimate medical purpose. ALJ–1, at 5–6, paras. 13–15. During the hearing the Government established by a preponderance of the evidence that Dr. Daniels did not perform, or he failed to document that he performed, a physical examination of CM. FF 166–67. Dr. Daniels also failed to obtain past medical records concerning CM. FF 168, 172; Tr. 198. Although the standard of care dictated that Dr. Daniels check CM's PMP, he did not do so. FF 26, 172. Although Dr. Daniels did conduct some urine drug screens of CM, there is no documentation of any action he may have taken concerning screenings that were abnormal. FF 158, 169, 170, 172. Finally, Dr. Daniels did not document within CM's medical record a rationale for the controlled substances he prescribed to CM. FF 166–67. Accordingly, *[I find based on the unrebutted, credible, expert testimony of Dr. Kennedy, and as supported by the evidence] that the prescriptions that Dr. Daniels issued to CM were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 172.

While the preponderance of the Government's evidence establishes that the medical records Dr. Daniels maintained on CM failed to provide an adequate justification for Klonopin, it did not establish the dangers of prescribing buprenorphine and Klonopin together, or that Dr. Daniels failed to caution CM of the dangers. FF 70. In fact, the Government presented no evidence that both buprenorphine and Klonopin are respiratory depressants. In addition, CM's medical records include a Patient Treatment Contract that CM signed that specifically warned CM of the dangers of taking buprenorphine and Klonopin together. FF 160. Nevertheless, the Government established by a preponderance of the evidence that, for a number of reasons, all of the prescriptions identified in Stipulation 31 were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. FF 172.

Accordingly, the allegations contained in Paragraph 12 of the Order to Show Cause that Dr. Daniels issued prescriptions to Patient CM in violation of La. Admin. Code tit. 48, Pt. I, §§ 5637, 5647, 5723, 5725, 5731 are SUSTAINED. Because the Government presented no evidence that established that buprenorphine and Klonopin (clonazepam) are respiratory depressants the allegations contained in Paragraphs 13–15 of the Order to Show Cause concerning CM are NOT SUSTAINED. Nevertheless, by sustaining the allegations contained in Paragraph 12, I have found that all of the prescriptions that Dr. Daniels wrote for CM, including those for buprenorphine and Klonopin, identified in Stipulation 31, were issued outside the course of acceptable medical practice and were not issued for a legitimate medical purpose. These violations weigh in favor of denying Dr. Daniels' pending application for a Certificate of Registration.

Undercover Patient TC

The Government alleged that Dr. Daniels issued a prescription to TC for 60 tablets of 8/2 mg Suboxone on September 13, 2017. ALJ–1, at 7, para. 18. It also alleges that this prescription was issued beneath the standard of care for the practice of medicine in Louisiana, and outside the usual course of professional practice in violation of 21 U.S.C. 841(a) and 842(a); 21 CFR 1304.04(a); and La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1). ALJ–1, at 7–8, paras. 18–19. The Government alleged that the prescription was issued outside the usual course of professional practice and was beneath the standard of care for the following reasons. First, Dr. Daniels failed to conduct a physical examination of TC. Second, Dr. Daniels failed to request TC's medical records concerning prior substance abuse or past treatment of substance abuse. Third, Dr. Daniels failed to obtain a PMP report concerning TC. Fourth, Dr. Daniels prescribed a high dose of Suboxone to TC who presented as an opioid naïve patient. Fifth, Dr. Daniels' medical record for TC failed to provide an adequate evaluation of TC's condition or a treatment plan. ALJ–1, at 7–8, para. 19.

During the hearing the Government established by a preponderance of the evidence that Dr. Daniels did not perform, or he failed to document that he performed, a physical examination of TC. FF 175, 186, 188, 198, 200. Dr. Daniels also failed to obtain past medical records concerning TC. FF 199, 200. Contrary to the Government's allegation, Dr. Daniels did obtain a PMP report concerning TC. FF 26. The results of the PMP report, however, are not contained in TC's medical record. FF 187. Dr. Daniels conducted a urine drug screen of TC, which did not reveal any controlled substances in his body. FF 175–76. During TC's first appointment with Dr. Daniels, he prescribed 60 tablets of 8/2 mg of Suboxone, one tablet to be taken twice a day. FF 194. Because TC was an opioid naïve patient, had TC taken the Suboxone as it was prescribed, *[Dr. Kennedy testified that] he could have become quite sick. FF 197. Finally, Dr. Daniels' treatment notes for TC do not document his rationale for the manner in which he initiated his treatment of TC. FF 195. Therefore, I *[I find based on the unrebutted, credible, expert testimony of Dr. Kennedy, and as supported by the evidence] that the prescription that Dr. Daniels issued to TC was issued outside the standard of care. FF 200–01.

Accordingly, the allegations contained in Paragraph 18–19 of the Order to Show Cause that Dr. Daniels issued prescriptions to Patient TC in violation of 21 U.S.C. 841(a) and 842(a); 21 CFR 1304.04(a); and La. Admin. Code tit. 46, Pt. LIII, § 2745(B)(1) are SUSTAINED. These violations weigh in favor of denying Dr. Daniels' pending application for a Certificate of Registration.

Pain Management Patient JW

Lastly, the Government alleged that Dr. Daniels' issuance of controlled substance prescriptions for pain management to JW exhibited several deficiencies, to include: The lack of a doctor-patient relationship; therapeutic duplication; failure to justify co-prescribing; and failure to justify increasing his methadone dosage. ALJ–1, at 6–7, paras. 16–17. At the hearing, however, the Government stated that with respect to Patient JW, it was only concerned with the prescriptions that Dr. Daniels wrote to JW for OxyContin.[25] Tr. 547–48.

[25] Testimony in support of the Government's position is consistent with the summarization of Dr.

Continued

The Government presented evidence that OxyContin is a long-lasting continuous release medication indicated for patients who need around-the-clock pain management. FF 213, 268. It is not appropriate to prescribe OxyContin to be taken ''as needed.'' *Id.* It is also not appropriate to prescribe OxyContin for break-through pain. *Id.* In fact, taking OxyContin for break-through pain or on an ''as needed'' basis could be dangerous. *Id.*

Dr. Daniels issued seven OxyContin prescriptions to JW. Stip. 35. The prescription that Dr. Daniels issued to JW on March 14, 2014, for OxyContin, was issued with instructions to take them as the medications are intended to be used, one tablet every 12 hours. FF 214. The prescriptions that Dr. Daniels issued to JW on March 28, 2014, April 11, 2014, April 25, 2014, May 9, 2014, May 16, 2014, and January 6, 2017, for OxyContin were issued with instructions that the OxyContin was to be taken every four to six hours for severe breakthrough pain. FF 215. Dr. Daniels acknowledges when he wrote instructions for JW to take the OxyContin every four to six hours, he did so by mistake. Tr. 211. Nevertheless, he did so five times in 2014, and once again in 2017. FF 215; Stip. 35. Even though Dr. Daniels acknowledges it was a mistake to issue the OxyContin in the manner that he did, [*Q] [''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, 28,662 (2015) (quoting *Paul J. Caragine, Jr.* 63 FR 51,592, 51,601 (1998).]

In light of the six separate prescriptions that Dr. Daniels wrote to JW for OxyContin, with instructions to take the medication once every four to six hours, *[I find based on the unrebutted, credible expert testimony of Dr. Kennedy, and as supported by the evidence] that these six prescriptions were not issued within the usual course of professional practice and were not issued for a legitimate medical purpose. Accordingly, the allegation that Dr. Daniels issued these six prescriptions beneath the standard of care in Louisiana and outside the usual course of professional practice in violation of Federal and State laws and regulations is SUSTAINED. Because the Government did not present evidence to support the specific allegations contained in Paragraphs 16–17 of the Order to Show Cause, those allegations are NOT SUSTAINED. The sustained allegation, however, weighs in favor of denying Dr. Daniels' current application.

Discussion and Conclusions of Law [*R]

Based upon my review of the evidence in this case, I have sustained the allegations that all of the prescriptions that Dr. Daniels issued to patients AK, CA, MN, JD, SB, CM, and TC, and six of the prescriptions Dr. Daniels wrote to patient JW, were issued outside the usual course of professional practice, and therefore were not issued for legitimate medical purposes. While these prescriptions were issued to only eight patients, Dr. Daniels wrote over 140 prescriptions to these patients during a 17-month period. My independent review of the medical records that Dr. Daniels maintained on all of these patients, except for JW, allows me to adopt fully Dr. Kennedy's testimony concerning the adequacy of those records. *[Based on Dr. Kennedy's expert testimony and the record evidence in this case] where there is a consistent absence of pertinent information in a patient's medical records, such as: PMP reports; a credible physical examination; past medical records; resolution of abnormal drug screens, the records reach a point where it is not possible to say that the treatment has been within the scope of acceptable medical practice or that the prescriptions are legitimate. FF 50.

Issues Raised by the Respondent

In explaining this Recommended Decision, it is appropriate to address two issues that Dr. Daniels raised both at the hearing and in his Post-Hearing Brief. In that Brief, Dr. Daniels repeatedly asserts that ''the Government presented no evidence that [the patient] was obtaining the same or similar prescriptions from multiple sources or obtaining those medications for illicit purposes.'' ALJ–19, at 11, 13, 15, 16, 17, 19. In addition, in his Brief, Dr. Daniels notes that Dr. Kennedy's opinions were based upon his review of a few charts and that ''[t]his miniscule sampling of six (6) charts hand picked by DEA should raise serious questions as to the legitimacy of any 'pattern' that may be deduced therefrom.'' *Id.* at 4–5.

Meaning of Diversion

Some of Dr. Daniels' arguments in his Brief reflect a misunderstanding of the DEA's definition of diversion. Dr. Daniels essentially contends that the Government did not present evidence of diversion. ALJ–19, at 11, 13, 15, 16, 17, 19. One of the CSA's primary purposes is to protect against ''the diversion of drugs from legitimate channels to illegitimate channels.'' *United States* v. *Moore,* 423 U.S. 122, 135 (1975). To ensure that controlled substances remain in legitimate channels, the CSA creates a ''closed regulatory'' scheme. *Gonzales* v. *Oregon,* 546 U.S. 243, 250 (2006). The DEA has explained that diversion occurs whenever controlled substances leave ''the closed system of distribution established by the CSA . . . .'' *Roy S. Schwartz,* 79 FR 34,360, 34,363 (2014). Thus, ''when prescriptions are issued outside of the usual course of professional practice and lack a legitimate medical purpose, . . . the drugs are deemed to have been diverted.'' *George Mathew, M.D.,* 75 FR 66,138, 66,148 (2010).

Contrary to Dr. Daniels' suggestion, the Government does not need to prove that a patient was seeking medications from multiple sources or was abusing controlled substances for a finding of diversion. Rather, when a practitioner violates the CSA's prescription requirement, set forth in 21 CFR 1306.04(a), by issuing a prescription without a legitimate medical purpose and outside the course of professional practice, the DEA [essentially] considers the prescription to have been diverted. *Mathew,* 75 FR at 66,146. *[Omitted for brevity.]

Although the DEA has occasionally considered such evidence,[26] the Government is not obligated to show, as the Respondent would suggest, that a patient died, overdosed, or illegally disposed of prescription medication.

Kennedy's testimony contained in the Government's Prehearing Statement, ALJ–5, at 25–26, and the Government's Supplemental Prehearing Statement. ALJ–9, at 3–4.

[*Q] Altered for clarity.

[*R] I am omitting the RD's discussion of material falsification because, as noted above, the Government has explicitly abandoned that allegation. *See supra* Analysis.III.

[26] *See, e.g. Lawrence E. Stewart, M.D.,* 81 FR 54,822, 54,832, 54847 (2016) (discussing registrant's treatment of patient who overdosed on prescriptions issued by the registrant); *Ibem R. Borges, M.D.,* 81 FR 23,521, 23,523 (2016) (suggesting that registrant's prescribing which caused overdose deaths could result in ''total revocation based on public interest grounds'', but deciding the case differently in accord with the allegations premised on lack of state authority); *Samuel Mintlow, M.D.,* 80 FR 3630, 3646 (2015) (noting expert testimony that respondent prescribed at such high dosages as to risk '''acute narcotic overdose'''); *Richard D. Vitalis, D.O.,* 79 FR 68,701, 68,701, 68,707 (2014) (considering evidence that respondent's patient died of overdose attributable to respondent's over-prescribing); *Darryl J. Mohr, M.D.,* 77 FR 34,998, 35,010–11 (2012) (discussing three patients who died due to registrant's prescribing).

Waiting for a controlled substance to be found coursing through a person's bloodstream before holding the registrant accountable is wholly at odds with the DEA's responsibility to protect the public interest under 21 U.S.C. 823(f). For these reasons, I reject Dr. Daniels' suggestion that the Government has not provided enough evidence to justify denying his application.

Size of the Sample

The DEA has made it clear that the Government may proceed to hearing with only a few allegations. ''[W]here the Government has seized files, it can review them and choose to present at the hearing only those files which evidence a practitioner's most egregious acts.'' *Jacobo Dreszer, M.D.,* 76 FR 19,386, 19,387 (2011); *see also Cleveland J. Enmon, Jr., M.D.,* 77 FR 57,116, 57,126 (2012) (rejecting argument that the respondent's practice could not be judged based upon a review of only 19 files). Furthermore, the DEA has held that ''even though the patients at issue are only a small portion of [a] [r]espondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding his ability to responsibly handle controlled substances in the future.'' *Paul J. Caragine, Jr.,* 63 FR 51,592, 51,600 (1998).

With respect to consideration given to a practitioner's positive experience in prescribing, the DEA assumes that all of the prescriptions a registrant has issued were issued lawfully, except for those prescriptions that the Government alleges were issued unlawfully. *Wesley Pope, M.D.,* 82 FR 14944, 14,984 (2017). *[The violations I have found demonstrate that Dr. Daniels repeatedly violated the applicable standard of care and state law and that his conduct was not an isolated occurrence, but occurred with multiple patients and in multiple contexts over a period of years. *See Kaniz Khan-Jaffery M.D.,* 85 FR 45,667, 45,685 (2020).]

Prima Facie Showing and Balancing

The Government can meet its burden for revocation or denial by proving ''only a few instances of illegal prescribing.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 464 (2009). DEA precedent asserts in no uncertain terms that the public interest inquiry is not a numbers game in which the Government must prove a certain number of violations.[27] For instance, in *Alan H. Olefsky, M.D.,* the DEA imposed a revocation based on evidence of only two fraudulent prescriptions.[28] 57 FR 928, 928–29 (1992). In *James Clopton, M.D.,* the DEA denied the respondent's application on evidence that he wrote only four unlawful prescriptions. 79 FR 2475, 2475–77 (2014). Although the record contained additional evidence of recordkeeping violations, the Administrator viewed the unlawful prescriptions as ''reason alone to deny [respondent's] application.'' *Id.* at 2478.

Additionally, in *Jose Gonzalo Zavaleta, M.D.,* the Administrator denied an application where the evidence showed a total of six unlawful prescriptions written on four occasions. 77 FR 64,128, 64,129–30 (2012). In *Gabriel Sanchez, M.D.,* the DEA based revocation on a total of seven prescriptions issued to two undercover officers who each had one appointment with the respondent. 78 FR 59,060, 59,060–61 (2013). In *Clair L. Pettinger, M.D.,* the Administrator revoked the registrant's COR based on evidence that he issued nine prescriptions in violation of 21 CFR 1306.04(a), and authorized one prescription while his COR was suspended. 78 FR at 61,600. In *MacKay* v. *DEA,* the Tenth Circuit affirmed revocation based on 14 unlawful prescriptions. 664 F.3d 808, 811–14, 822 (10th Cir. 2011). In *Wesley Pope, M.D.,* the Administrator deemed denial the appropriate sanction where the Government proved violations stemming from 19 unlawful prescriptions. 82 FR at 14,985. In *Lynch* v. *DEA,* the Eleventh Circuit upheld revocation based on evidence of 19 unlawful prescriptions. 480 Fed. App'x 946, 948 (11th Cir. 2012) (unpublished) (per curium) (reviewing *Ronald Lynch, M.D.,* 75 FR 78,745 (2010)).

These cases represent only a sampling of DEA final orders, but they illustrate the point that the Administrator has imposed the DEA's harshest sanction—revocation or denial—based on evidence of only 2 to 19 unlawful prescriptions. The present case involves over 140 prescriptions.[*S]

Summary of Factors One, Two and Four

Specifically, the Government bases its case on evidence that implicates Factors Two and Four of 21 U.S.C. 823(f). The Government did not advance any evidence under Factors One, Three, and Five. As the DEA has explained, ''findings under a single factor are sufficient to support the revocation or suspension of a registration.'' *Syed Jawed Akhtar-Zaidi, M.D.,* 80 FR 42,962, 42,967 (2015). While I consider all the factors, the central inquiry ''focuses on protecting the public interest,'' and misconduct relevant to only one factor can be sufficient to support a finding that a practitioner's continued registration threatens the public interest. *Id.*

[I have found that there is substantial evidence in the record before me that Dr. Daniels issued controlled substance prescriptions to eight individuals, including for Schedule II controlled substances, for no legitimate medical purpose and outside the usual course of professional practice, that Respondent failed to maintain medical records pertaining to his prescribing of controlled substances in violation of state law and the state standard of care. Accordingly, I conclude that it would be ''inconsistent with the public interest'' for Dr. Daniels to be granted a registration due to the substantial evidence of his violations of the CSA and its implementing regulations and state law. 21 U.S.C. 823(f).]

Based on the evidence in this case, *[I have found that Factor One weighs slightly] against denying Dr. Daniels' application. Factors Two and Four, however, weigh for denying his application. Considering the public interest factors in their totality, I find that the Government has made a *prima facie* case showing that Dr. Daniels' registration would be inconsistent with the public interest.

[*T] Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Dr. Daniels' application for a registration is inconsistent with the public interest due to his violations of federal and state law pertaining to controlled substance prescribing, the burden shifts to the Dr. Daniels to show why he can be entrusted with a new

[27] *See Lawrence E. Stewart, M.D.,* 81 FR 54,822, 54,848 (2016) (stressing that even though the respondent committed ''far more than one'' violation, proving only one instance of knowing diversion is enough to make a *prima facie* case for revocation); *T.J. McNichol, M.D.,* 77 FR 57,133, 57,145 (2012) (''[P]roof of a single act of intentional or knowing diversion is sufficient to satisfy the Government's *prima facie* burden . . . .''); *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009) (emphasizing that ''what matters is the seriousness'' of the misconduct rather than a tallying up of violations).

[28] Additionally, in the *Olefsky* case, the registrant argued in his exceptions to the ALJ's recommended ruling that suspension of his license was disproportionate to the proven misconduct, which was limited to two fraudulent prescriptions presented on one occasion. 57 FR at 929. The Administrator rejected the registrant's exception and ruled that ''[r]evocation [was] an acceptable remedy.'' *Id.*

[*S] Omitted for brevity.

[*T] I am replacing portions of the Sanction section in the RD with preferred language regarding prior Agency decisions; however, the substance is primarily the same. I will also address Dr. Daniels' Exceptions herein as noted.

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 argument Respondent submitted to determine whether or not he 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 at 463 (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).]

Dr. Daniels may accept responsibility by providing evidence of his remorse, his efforts at rehabilitation, and his recognition of the severity of his misconduct. *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,228 (2003). To accept responsibility, a respondent must show ''true remorse'' for wrongful conduct. *Michael S. Moore, M.D.,* 76 FR 45,867, 45,877 (2011). An expression of remorse includes acknowledgment of wrongdoing. *Wesley G. Harline, M.D.,* 65 FR 5665, 5671 (2000). A respondent must express remorse for all acts of documented misconduct. *Jeffrey Patrick Gunderson, M.D.,* 61 FR 26,208, 26,211 (1996). Acceptance of responsibility and remedial measures are assessed in the context of the ''egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.'' *David A. Ruben, M.D.,* 78 FR 38,363, 38,364 (2013).

Notwithstanding the fact that the Government has made a *prima facie* case for sanction, imposing a sanction is a matter of discretion. *See* 21 U.S.C. 824(a) (''A registration . . . *may* be suspended or revoked by the Attorney General . . . .'') (emphasis added); *Martha Hernandez, M.D.,* 62 FR 61,145, 61,147 (1997) (referring to Administrator's authority to exercise discretion in issuing the appropriate sanction).[*T]

[*U] [Respondent argues in his Exceptions that he ''acknowledged responsibility throughout the proceedings.'' Resp Exceptions, at 2. In support of this statement, he cites to the record [*V] where he ''agreed with DEA's expert, Dr. Kennedy's testimony about the importance of physical examinations.'' *Id.* (citing Tr. 492). Although I credit Dr. Daniels for agreeing with the Government's expert regarding the standard of care, he then went on to state that in situations where there is limited staff and when other patients are waiting, a doctor sometimes needs to make a ''judgment call'' about examining the patient, and not inconveniencing the waiting patients. Tr. 493. In those situations, in Dr. Daniels' view, the doctor performs ''enough of an exam'' in order to ''move forward'' with the patient, allowing the doctor time to see other patients. Tr. 493. After agreeing with the Government's expert that ''a physical examination is certainly very important,'' Tr. 492, which in this case is required by state law, Dr. Daniels then proceeded to try to minimize his misconduct in not conducting the required, self-described ''very important'' physical examinations by implying that a practitioner could ignore a legal requirement for one patient in order to not ''inconvenience other patients who may be waiting.'' Tr. 493. Not only do I find this statement to minimize any acceptance of responsibility, I find it to be in blatant disregard of the ''importan[ce]'' of a physical examination.[*W] *See Stein,* 84 FR at 46,972 (finding that a registrant's attempts to minimize his misconduct weigh against a finding of unequivocal acceptance of responsibility); *see also Ronald Lynch, M.D.,* 75 FR 78,745, 78,754 (2010) (Respondent did not accept responsibility noting that he ''repeatedly attempted to minimize his [egregious] misconduct''); *Michael White, M.D.,* 79 FR 62,957, 62,967 (2014) (finding that Respondent's ''acceptance of responsibility was tenuous at best'' and that he ''minimized the severity of his misconduct by suggesting that he thinks the requirements for prescribing Phentermine are too strict.''). It does not instill confidence in me that Dr. Daniels could be entrusted with a registration when he could so casually dismiss a legal requirement based on a perception of inconvenience to other patients.

Further, when explaining the reasons for his Consent Agreement with the Medical Board, Dr. Daniels stated that the Board ''felt like that [he], as an individual practitioner, trusted people too much, that [he] gave too much confidence in the people when [he] would ask them to do things or expect them to bring things to [him].'' Tr. 561. If the violations before the Medical Board were similar to the ones before me, as the record suggests, I find this to be an outrageously minimized characterization of his wrongdoing. Dr. Daniels subtly passes the blame onto his co-workers at the clinic and characterizes himself as too trusting. Based on this statement, it does not appear to me that Dr. Daniels

[*T] Omitted for brevity.

[*U] The ALJ found that thee was ''no evidence that Dr. Daniels has accepted any responsibility for the 141 prescriptions he issued to eight different patients. The closest he came to accepting responsibility was an acknowledgement that 'some of the records fell short.' Tr. 570.'' RD, at 98. Although I agree with the ALJ that ultimately Respondent did not adequately accept responsibility, Respondent has taken exception to this finding and therefore I am evaluating Respondent's additional citations to the record in support of his statement that he ''acknowledged responsibility throughout the proceedings.'' Resp Exceptions, at 2.

[*V] Dr. Daniels also cited to page 11 of the Transcript to support that he had ''acknowledged that he did not always document the justification for the prescriptions that he wrote,'' but I could not find what he was referencing. Resp Exceptions, at 2.

[*W] I also found above that Dr. Daniels misstated his conversations with TC regarding alcohol use that he had counseled TC not to drink alcohol, TR. 555, despite the fact that the record directly contradicts this statement. Again, I find that this is an attempt to minimize the egregiousness of his interaction with TC and weighs against a finding of acceptance of responsibility.

comprehends the full extent of his wrongdoing in order for me to find acceptance of responsibility. Furthermore, it demonstrates that, thus far, he has not learned from his mistakes in order to be deterred from repeating them.]

[The ALJ found that the] closest [Dr. Daniels] came to accepting responsibility was an acknowledgment that ''some of the records fell short.'' Tr. 570. Then in his Brief, Dr. Daniels admits that ''the documentation of the patient files needed much improvement.'' ALJ–19, at 22. He adds, however, that ''poor documentation is not evidence that the prescriptions were written for illegitimate purposes.'' [29] *Id.* *[Again, Dr. Daniels minimizes his misconduct, and additionally, this statement critically understates the egregiousness of his found wrongdoing, which is more serious than poor documentation, as explained below. I agree with the ALJ that these admissions do not amount to acceptance of responsibility. *See Carol Hippenmeyer, M.D.,* 86 FR 33,748, 33,773 (2021) (''Respondent's admission that she failed to maintain adequate medical records was not a sufficient acceptance of responsibility.''); *see also Kaniz F. Khan-Jaffery, M.D.,* 85 FR 45,667, 45,686 (2020) (''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.'')

I further find that the additional cites to the transcript that Dr. Daniels references in his Exceptions, also do not amount to adequate acceptance of responsibility. *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''). Although Dr. Daniels admitted that he made a ''mistake'' on the instructions for JW's OxyContin prescriptions, Tr. 549, he also stated that he thought JW ''was taking it correctly,'' Tr. 550, based on the fact that he did not run out between visits; however, Dr. Daniels never acknowledged the severity of the consequences that could have occurred had JW taken them pursuant to his mistaken instructions. Tr. 273 (Dr. Kennedy's testimony that taking OxyContin pursuant to Dr. Daniels instructions would be ''very dangerous'' and that the controlled substance had a ''black box'' warning regarding those dangers.)

Further, even if Respondent's acceptance of responsibility for his wrongdoing had been sufficient such that I would reach the matter of remedial measures, Respondent has not offered adequate remedial measures to assure me that I can entrust him with a registration. *See Carol Hippenmeyer, M.D.,* 86 FR 33,748, 33,773 (2021). Dr. Daniels stated that as a result of the Consent Order, he took ''a controlled substance prescribing course in Cleveland, Ohio at Case Western Reserve University, ethics, boundaries, those were recommended. I did complete those,'' Tr. 562, however, he did not submit any documentation regarding these courses, and I do not find that he presented any meaningful evidence regarding actual or proposed remedial measures, other than the possibility of limiting his registration to Schedule V controlled substances. *See infra* n.30.]

''[E]ven though the Government has made out a *prima facie* case'' for sanction, the registrant remains free to argue that ''his conduct was not so egregious as to warrant revocation.'' *Jacobo Dreszer, M.D.,* 76 FR 19,386, 19,387–88 (2011). ''In short, this 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.'' *Richard J. Settles, D.O.,* 81 FR 64,940, 64,945 n.17 (2016) (quoting *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009)).

*X [ ] The Administrator has noted that ''there may be some instances in which the proven misconduct is not so egregious as to warrant revocation . . . and a respondent, while offering a less than unequivocal acceptance of responsibility[,] nonetheless offers sufficient evidence of adequate remedial measures to rebut the Government's proposed sanction.'' *Roberto Zayas, M.D.,* 82 FR 21410, 21429 (2017). This is not such an instance.

*[In this case, the ALJ found, and I agree, that there was substantial record evidence that over 140 prescriptions issued by Respondent were issued outside the usual course of professional practice and beneath the standard of care. Specifically, the Government's credible expert witness testified that certain conduct was particularly egregious. For example, he described one of the urine drug screens for Patient MN, which was positive for ecstasy, as ''wildly abnormal,'' Tr. 225, and he stated that ''to have a drug screen like this, and to make absolutely no comment in the medical record, did not make any comment with addressing the patient about it, or what you plan to do about this, is in my view, inexcusable.'' Tr. 226. Further, Dr. Kennedy testified regarding Patient SB's records that ''there was, in essence, in [his] view, no medical care here, simply the provision of scheduled prescriptions.'' Tr. 244. Dr. Kennedy also testified several times that there was no medical diagnosis at all in the records to support controlled substance prescriptions. *See e.g.,* Tr. 396–97; GE–6, at 1–49 (no justification for Klonopin to AK); Tr. 322, 377 (no justification for Adderall to CA). Dr. Daniels prescribed controlled substances to AK and CA without maintaining any records on his visits with them, if they occurred. He repeatedly failed to conduct physical examinations, address urine drug screens, and counsel patients about risks. The Government's expert, Dr. Kennedy, testified that in addiction treatment, these accountability measures were of particular importance, ''not because we're counting on the patients being compliant, it's because of the likelihood of patients being noncompliant.'' Tr. 299. Although I find Dr. Daniels to be sincere and laudable in his wish to help an underserved population, it does not excuse his repeated failure to follow the laws designed to keep these patients safe.]

In addition to the severity of the proven misconduct, DEA also considers its interest in specific and general deterrence when determining the appropriate sanction. *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,810 (2015); *David A. Ruben, M.D.,* 78 FR 38,363, 38,364 (2013). Deterrence is an appropriate consideration, and is consistent with the CSA's purpose of protecting the public interest and the DEA's broad grant of authority to consider acts inconsistent with the public interest. *Southwood Pharm., Inc.,* 72 FR 36,487, 36,504 (2007). General deterrence concerns DEA's

[29] This statement demonstrates Dr. Daniels' lack of understanding of the need to maintain adequate medical records. First, the State of Louisiana requires it. La. Admin. Code tit. 46, Pt. LIII, § 6921(B)(6); La. Admin. Code tit. 48, Pt. I, § 5637 (A)–(B). Second, when a practitioner fails to maintain adequate medical records that practitioner is not acting within the usual course of professional practice. Third, as noted earlier in this Recommended Decision, a controlled substance prescription is valid only when it 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) (emphasis added).

*X Omitted for brevity.

responsibility to deter conduct similar to the proven allegations against the respondent for the protection of the public at large. *Glick,* 80 FR at 74,810. Specific deterrence is the DEA's interest in ensuring that a registrant complies with the laws and regulations governing controlled substances in the future. *Id.*

Having considered all of the evidence, I find that Dr. Daniels' violations of federal and state laws and regulations concerning the prescribing of controlled substances were egregious. I concur with Dr. Kennedy's assessment of the adequacy of Dr. Daniels' medical records concerning patients, AK, CA, MN, JD, SB, CM, and TC, not only because his expert testimony went unrebutted, but also *[because a review of the sparse medical records demonstrates obvious deficiencies, to include no records at all related to some of the prescriptions]. I also find Dr. Daniels' statement that poor documentation is not evidence of illegitimate prescriptions to be a further indication demonstrating his continuing lack of understanding of the responsibilities of an individual who holds a Certificate of Registration.

Further, I find it appropriate to consider both general and specific deterrence. In light of the extremely poor quality of the medical records that Dr. Daniels maintained, which were non-existent in some instances, and the fact that he continues to attempt to portray his records as adequate to support his prescriptions for controlled substances, to include Schedule II and III substances, granting his application would send the wrong message to other medical practitioners. In addition, granting a Certificate of Registration to Dr. Daniels, absent his acceptance of responsibility and an acknowledgement of the responsibilities attached to a registration, would totally defeat the concept of specific deterrence.

* [Here, 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.''). Due to the extent and egregiousness of Dr. Daniels' misconduct, his failure to adequately accept responsibility, Dr. Daniels has not given me reassurance that he can be entrusted with a registration.]

Therefore, I find that granting a Certificate of Registration to Dr. Daniels, at this time, would be inconsistent with the public interest.[30]

[30] I have given consideration to recommending that Dr. Daniels' application be granted, but limited to Schedule V, to accommodate his current medical practice. *See supra* FF 8. While Dr. Daniels' continued efforts to provide medical assistance to underserved communities is commendable, there is insufficient evidence in the Administrative Record to support such a recommendation. *[I agree, and I disagree with Respondent's Exception stating that ''limitation to Schedule V would protect the public interest since he will not be practicing in high risk areas.'' Resp Exceptions, at 3. Respondent has not provided me with adequate reasons to entrust him with a controlled substance registration at any schedule.]

Recommendation

Accordingly, I *Recommend* that Dr. Larry C. Daniels' application for a DEA Certificate of Registration, Control Number W18024499C, be *Denied*.

Dated: January 24, 2020.

Charles Wm. Dorman,

U.S. Administrative Law Judge.

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 pending application for a Certificate of Registration, Control Number W18024499C, submitted by Larry C. Daniels, M.D., as well as any other pending application of Larry C. Daniels, M.D. for additional registration in Louisiana. This Order is effective December 6, 2021.

Anne Milgram,

Administrator.

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